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Quick Chemical Assessment Tool
Version 1.3

By Alex Stone, Sc. D.

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For more information contact:

Hazardous Waste & Toxics Reduction Program
PO Box 47600
Olympia, WA 98504-7600
Phone: 360-407-6700

Washington State Department of Ecology - www.ecy.wa.gov

○ Headquarters, Olympia	360-407-6000
○ Northwest Regional Office, Bellevue	425-649-7000
○ Southwest Regional Office, Olympia	360-407-6300
○ Central Regional Office, Yakima	509-575-2490
○ Eastern Regional Office, Spokane	509-329-3400

Disclaimer:
Although the Quick Chemical Assessment Tool is based on methodology developed by the United States Environmental Protection Agency's (EPA) Design for the Environment (DfE) program subsequently adapted by Clean Production Action as the GreenScreen™, this should not be taken as an endorsement of the Quick Chemical Assessment Tool by either organization. The Quick Chemical Assessment Tool remains the product of the Washington State Department of Ecology who is responsible for its contents and implementation.

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By Alex Stone, Sc. D.
Washington State Department of Ecology
Olympia, Washington

Table of Contents

Tables

Figure

1. Introduction

As concern has increased about the widespread use of toxic chemicals in products and the overall effect these chemicals have upon human health and the environment, issues have arisen around the replacement of these chemicals of concern with safer alternatives. Previously, there have been several instances where chemicals of concern were replaced with chemicals shown to pose an equal or greater hazard than the original. This process is called 'regrettable substitution.'

One well-documented example of regrettable substitution is the replacement of chlorinated solvents in the auto repair industry with hexane. (CDC, 2001) In response to increasing regulation of methylene chloride and other halogenated solvents, several manufacturers switched from chlorinated solvents to hexane for products, such as brake cleaners without determining if any hazards were associated with the substitute. Hexane was known to cause nerve damage as early as 1964. (Yamada, 1964) A few years after the substitution, workers in auto repair shops in California began to report health concerns that were eventually tied to hexane. (Berkeley, 2010) Examples like this emphasize the need for methodologies to compare chemicals of concern with potential substitutes to guarantee that products are both toxic free and safe for use.

The U.S. Environmental Protection Agency (EPA) took the early lead in this field and established the Design for the Environment (DfE) Program in the late 1990s. DfE pioneered work in the field of alternatives assessments by developing a series of hazard criteria used to compare chemicals of concern with potential substitutes. DfE revised the hazard criteria in 2011. These criteria formed the basis of the methodology DfE continues to use in its alternatives assessment program. (DfE, 2011)

In addition, DfE established a voluntary program with several manufacturers of consumer products and, by comparing these criteria, created the DfE labeling program. Ingredients in these DfE labeled products have undergone extensive review by DfE. Each ingredient in the formulation has the lowest possible impact on human health and the environment in their functional class while maintaining product functionality at a reasonable cost. Since the inception of the labeling program, more than 2,500 products carry the DfE label. (DfE, 2014)

Other organizations have taken the DfE hazard criteria and alternatives assessment process and adapted them for use by a wider audience. A non-profit organization, Clean Production Action (CPA) was one of the earliest adopters. CPA adapted the DfE criteria and methodology and created the GreenScreen® for Safer Chemicals (GS®), a tool that emphasizes transparency during the alternatives assessment process. (CPA, 2012) CPA tested the new GS® methodology by conducting an alternatives assessment of the flame retardant, decabromodiphenyl ether. (CPA, 2007) Several companies and organizations, including the Washington State Department of Ecology (Ecology), have adopted the GS® as a tool for conducting chemical hazard assessments (CHA) in their alternatives assessment process.

Ecology used the GS® during its assessment of decabromodiphenyl ether use in electronic enclosures and residential upholstered furniture. (Ecology, 2009) Other organizations also using the GS® include the Green Chemistry and Commerce Council (GC3, 2012) and Hewlett-Packard (Lavoie, 2010).

A CHA is only part of an alternatives assessment process as other factors such as performance, cost, availability, exposure, etc. may affect the viability of alternatives. The Interstate Chemicals Clearinghouse (IC2) published an Alternative Assessment Guide (AA Guide) in 2014. (IC2, 2014) The guide describes recommended AA processes, including three frameworks and ten modules to consider during development of an AA. The GS® and QCAT are included as different levels within the CHA module of the IC2 AA Guide.

Although these excellent tools provide the highest degree of certainty against a regrettable substitution, they require a high level of technical expertise and resource allocation. These limitations make it very difficult for small and medium businesses with limited resources and expertise to conduct any degree of alternatives assessment. It is for this reason that Ecology began developing the Quick Chemical Assessment Tool (QCAT).

The QCAT is based on the GS® although it is neither as comprehensive nor as detailed in its evaluation. The objective, however, is to provide a simpler tool that smaller businesses can implement and at least have some degree of assurance they are not replacing one toxic chemical with another already identified as having hazard concerns. Because the QCAT is less comprehensive than the GS®, there is a greater risk of making a regrettable substitution than if a full GS® is conducted. Given that limitation, the QCAT has three primary advantages. It:

1. Increases familiarity with the alternatives assessment process.
2. Helps identify chemicals that are clearly poor substitutes.
3. Helps dedicate limited resources to a more comprehensive alternatives assessment on those alternatives that look most promising.

Since the QCAT is based on the GS®, we will first provide an overview of the GS®, followed by a detailed description of the QCAT including how the QCAT is similar and different from the GS®, and how to use the QCAT.

2. GreenScreen™ Background

The GS® evaluates chemicals and their potential degradation products against a wide range of toxicity, environmental fate, and physical/chemical endpoints to determine safer alternatives to chemicals of concern. Chemicals receive a benchmark score based upon the combination of the hazard assessments of 19 endpoints (18 required and 1 optional):

Hazard Criteria

Human Health Effects

Group I	Group II
• Carcinogenicity (C) • Mutagenicity & Genotoxicity (M) • Reproductive Toxicity (R) • Developmental Toxicity (including Developmental Neurotoxicity) (D) • Endocrine Activity (E)	• Acute Mammalian Toxicity (AT) • Systemic Toxicity & Organ Effects (including Immunotoxicity) (ST) • Neurotoxicity (N) • Sensitization: Skin (SnS) • Sensitization: Respiratory (SnR) • Irritation/Corrosivity: Skin (IrS) • Irritation/Corrosivity: Eyes (IrE)

Environmental Health

- Acute Aquatic Toxicity (AA)
- Chronic Aquatic Toxicity (CA)
- Other Ecotoxicity Studies, when available (optional except for BM 4) (Eo)

Environmental Fate

- Persistence (P)
- Bioaccumulation (B)

Physical/Chemical Properties

- Reactivity (R)
- Flammability (F)

The GS® requires a high level of technical expertise as specialists in toxicology, chemistry, computer modeling, and other scientific areas generate data, evaluate sources, review technical information, and assign benchmark scores to the chemicals that have undergone the screening process. This is particularly true when information from peer-reviewed journal articles and computer modeling are used to provide data for hazard endpoints.

The GS® also requires a commitment of time and resources and, therefore, is costly to implement. To address these concerns, the GS® coordinates with other regulatory requirements (GHS,[1] REACH,[2] etc.) and uses authoritative lists to provide established criteria for those chemicals for which toxicity concerns have already been identified. This enables different individuals and organizations to implement the GS® and reach similar conclusions, i.e., consistent results from different individuals and/or organizations

[1] The United Nation's Global Harmonization System. GHS requires labeling of chemicals for a wide range of hazard criteria.
[2] The European Union's Registration Evaluation and Authorisation of CHemicals legislation. REACH establishes data requirements for any chemical manufactured or imported into the European Union.

performing an assessment on the same chemical using 'professional judgment.' If data are not available using easily accessible sources requiring little user interpretation, more technical sources requiring a higher level of interpretation are used to provide a complete data set for comparison.

As with many aspects of the GS®, the level of expertise required to evaluate data and determine whether it can be used increases as the data sources become more technical and detailed. Individuals with specialized degrees may be needed such as toxicologists, chemists, (Q)SAR[3] specialists, etc. to provide a professional evaluation of specific sources. For example, Ecology commissioned SRC (formerly Syracuse Research Corporation) to collect data and generate (Q)SAR data addressing hazard endpoints and other toxicity data for Ecology's chemical action plan (CAP) on the polybrominated diphenyl ether (PBDE) family of flame-retardants. (Ecology, 2006) The data was subsequently used in the deca-BDE alternatives assessment.

Based upon this detailed scientific evaluation, the GS® provides the highest degree of certainty that the CHA is valid and comprehensive. Because of the evolving nature of science, some degree of uncertainty will exist for any hazard evaluation methodology including the GS®. All chemicals and products should be subjected to periodic review to evaluate the impact of improvements in data and scientific understanding upon the classification of chemicals and the final benchmark assigned from a particular evaluation.

The GS® places chemicals along a continuum of concern and assigns each chemical one of four possible benchmarks (Table 1):

Table 1: Benchmarks from the GS® Assessment Process

Benchmark 4	Few concerns, i.e., safer chemical	**Preferable**
Benchmark 3	Slight concern	**Improvement possible**
Benchmark 2	Moderate concern	**Use but search for safer**
Benchmark 1	High concern	**Avoid**

This benchmarking process identifies chemicals as safer alternatives to existing chemicals of concern. It also emphasizes the removal of chemicals of high concern (Benchmark 1) from the manufacturing stream and product design. Benchmark 1 chemicals are typically one or more of the following:

1. Persistent, bioaccumulative, and toxic (PBT).
2. Very persistent and very bioaccumulative (vPvB).
3. Identified as a high level hazard for a priority human health effect such as CMR (carcinogenicity, mutagenicity, or development toxicity), etc.

Based on this analysis, safer alternatives to chemicals of concern are identified in a clear and reproducible manner.

[3] (Q)SAR = Quality Structure Activity Relationships. (Q)SARs are computer modeling results that predict the toxicity of chemicals based upon structural similarities with chemicals possessing known toxicity concerns.

3. Quick Chemical Assessment Tool

Because of the high level of technical and resource commitments required by the GS®, a simpler alternative called the Quick Chemical Assessment Tool has been developed by Ecology. The primary goal of the QCAT is to assign an appropriate grade for a chemical using a subset of high priority hazard endpoints identified in the GS® and fewer data sources. This information provides an approximation of the concerns associated with chemicals, based upon the limited data used in the evaluation process.

Because a QCAT assessment is based upon fewer data, chemicals with concerns could be missed during the evaluation process. In other words, the degree of uncertainty associated with the QCAT assessment is greater than with a GS® review. In a GS® assessment, data are obtained and evaluated for each of the 19 hazard endpoints. QCAT assessments examine nine of these hazard endpoints, which include priority human health effects (six endpoints), persistence, bioaccumulation, and acute aquatic toxicity. These nine endpoints identify a level of concern for each chemical.

The QCAT provides a quick and easy method to identify chemicals that are equally or more toxic than the chemical being reviewed. Limited resources can quickly identify chemicals that are not viable safer alternatives to the chemical of concern. Because of the reduced amount of information assessed, a QCAT does not identify preferable alternatives to the chemical of concern. If resources are limited, QCAT can be used to eliminate non-viable alternatives and remaining resources can be used to investigate the chemicals that pass a QCAT review.

The QCAT places chemicals along a continuum of concern and assigns each chemical one of four possible grades (Table 2):

Table 2: Grade Levels from the QCAT Assessment Process

Grade A	Few concerns, i.e., safer chemical	**Preferable**
Grade B	Slight concern	**Improvement possible**
Grade C	Moderate concern	**Use but search for safer**
Grade F	High concern	**Avoid**

The QCAT grading system is substantively different from the GS® benchmarking system. The differences emphasize that the QCAT is not as comprehensive as the GS® and that the risk of assigning an incorrect grade is greater. The QCAT clearly identifies Grade F (red) chemicals that should be targeted for removal from the manufacturing stream.

A secondary goal of the QCAT is to identify and prioritize additional research required to conduct a GS® assessment. The QCAT identifies chemicals of concern that could be used to prioritize chemicals at a particular manufacturing facility for a more detailed review. These chemicals of concern are separate from others that do not require immediate attention.

Evaluating chemicals using the QCAT provides several advantages. The QCAT focuses on important hazard endpoints, lowers data requirements, and provides a significant amount of information with a relatively low investment of resources in comparison to a GS® assessment. There are disadvantages of performing a QCAT rather than a GS® assessment. With its focus on a few endpoints, not all hazard endpoints are evaluated. An endpoint of concern could be overlooked either because the screening assessments did not highlight the endpoint or because new data are available that have not yet been reviewed by key information sources.

For example, new carcinogenicity data may be available on a chemical that has not yet been reviewed by the International Agency for Research on Cancer (IARC) or EPA. A GS® would include more recent information missed by the QCAT. The QCAT also provides less breadth and depth in evaluating data to determine levels of concern for hazard endpoints. Thus, performing a GS® assessment using a comprehensive weight of evidence approach with all available data may result in a different level of concern being assigned than by a QCAT.

Lastly, as more hazard information becomes available via the implementation of such regulations as the European Union's REACH and the Global Harmonization System, data may become available that was not used in the QCAT evaluation. This new data may alter the conclusions reached; therefore, users should revisit QCAT evaluations periodically and update them as necessary. Even with its limitations, the QCAT is a useful initial step in assessing chemical alternatives.

A. Use of Chemical Abstract Services (CAS) Number(s)

The QCAT is based on the Chemical Abstracts Service's (CAS) numbers. CAS numbers are assigned by the American Chemical Society and are unique to a specific chemical. Although a chemical may have many different common or product names, it typically has only one CAS number. Occasional errors do occur and, although a few chemicals may have more than one CAS identifier, it should have minimal impact upon the QCAT assessment process.

CAS numbers reduce confusion caused by varying and numerous chemical names. CAS numbers may be readily available from the chemical supplier. If a CAS number is not readily available, it may be obtained from the Hazardous Substances Database (HSDB), the Registry of Toxic Effects of Chemical Substances (RTECS), or other authoritative sources. Information on these three sources is available in Appendix 2. If unsuccessful, the CAS number may be obtained from an internet search. Without a CAS number, a specific chemical cannot undergo assessment.

B. QCAT Hazard Endpoints

Specific hazard endpoints used in QCAT are a subset of those in the GS® (Table 3). With the exception of endocrine activity, the QCAT hazard endpoints are the most widely studied and likely to be reported in QCAT data sources. QCAT prioritizes five categories of compounds:

1. Carcinogenic, mutagenic, and reproductive toxic compounds (CMRs)
2. Persistent, bioaccumulative, and toxic compounds (PBTs)
3. Acute environmental toxic compounds (acute aquatic toxicity)

4. Worker health and safety (acute mammalian toxicity)
5. Endocrine active compounds (developmental and reproductive)

Although authoritative data on endocrine activity are scarce, current research suggests endocrine active compounds have widespread negative impact on human health and the environment and, therefore, warrant inclusion. These criteria coincide with Ecology priorities as shown in legislation such as the Children's Safe Product Act and initiatives such as the Puget Sound Partnership and Reducing Toxic Threats.

Table 3: QCAT Hazard Endpoints Compared with the GS®

	QCAT	GS®
Human Health:		
Tier I		
Carcinogenicity (C)	X	X
Mutagenicity & Genotoxicity (M)	X	X
Reproductive toxicity (R)	X	X
Developmental toxicity (incl. developmental neurotoxicity) (D)	X	X
Endocrine activity (E)	X	X
Tier II		
Acute Mammalian Toxicity (AT)	X	X
Systemic & organ effects toxicity incl. Immunotoxicity (ST)		X
Neurotoxicity (N)		X
Sensitization: Skin (SnS)		X
Sensitization: Respiratory (SnR)		X
Irritation & Corrosivity: Skin (IrS)		X
Irritation & Corrosivity: Eye (IrE)		X
Ecological:		
Acute Aquatic Toxicity (AA)	X	X
Chronic Aquatic Toxicity (CA)		X
Other Ecotoxicity Studies (optional except for Benchmark 4) (Eo)		X
Environmental:		
Persistence (P)	X[4]	X
Bioaccumulation (B)	X	X
Physical:		
Reactivity (R)		X
Flammability (F)		X

The fewer endpoints clearly distinguish a QCAT from a GS® assessment. By including a wider range of hazard endpoints and requiring more detailed evaluation of the hazards involved, the GS® provides a greater degree of certainty concerning the hazards associated with each chemical.

There is a greater risk that chemicals of concern may be missed by the QCAT. However this increased risk is compensated for by the improved ability to implement the QCAT and reduced implementation costs. The QCAT also enables users to begin to understand the safer chemical alternatives process.

[4] Not needed as inorganics are assumed to be persistent. Clean Production Action is creating specialized rules for dealing with inorganic compounds. They will be incorporated into future QCAT updates.

The QCAT only looks at hazard-related criteria. Most alternatives assessments must consider other factors such as process engineering, availability, existing usage, cost, energy balance, exposure, etc. Although the CHA and specifically QCAT are important components of an alternatives assessment, other factors should be considered before identifying a safer alternative.

C. QCAT Data Sources

Authoritative lists and summarized data sources leverage expert judgment and provide a reliable initial assessment of the hazards considered in evaluating a chemical. Data sources used to complete the QCAT for the nine hazard endpoints are selected in two steps. From authoritative sources, Step I leverages hazard lists and Step II uses specific databases and documents. These steps (Table 4) are not unique to the QCAT but are informed by GS® and DfE data requirements.

Table 4: Two Steps of Data Collection for the QCAT

Data sources
Step I: Authoritative Sources: Toxicity characteristics lists, databases, etc. generated by internationally recognized authoritative bodies or appropriate government agencies.
Step II: Other Data Sources Estimated Data: PBT Profiler, other non-sophisticated modeling tools. Measured data: Specific information from publicly available risk assessments and databases such as RTECS, ECOTOX, HSDB, etc.

Each step requires an increasing level of technical expertise. For example, Step I sources require little technical review or expertise and only a basic understanding of the hazard endpoints. The user simply determines whether a chemical appears on an authoritative list created by recognized experts in the field. Step II requires sufficient technical expertise to evaluate data in the sources and reach a defensible conclusion about the applicability of the data. The QCAT includes instruction on how to find and interpret data from Step II sources. This reduces the need for technical expertise. A GS® evaluation (not included) requires experts knowledgeable and experienced in evaluating specific hazard endpoints. These advanced steps will not be used during a QCAT evaluation as this level of technical expertise is outside the QCAT's scope.

Chemicals identified in Step I sources do not need further evaluation. Presence in a Step I source is deemed authoritative and is sufficient for assigning a rank. **Only chemicals that do not appear in Step I sources continue to Step II.** For Step II sources, two or more individual sources should agree on the rank. If only one Step II source is available, a rank can still be assigned; however, the QCAT report should document any limitations and indicate further review might be warranted.

In QCAT, Step II databases and documents are searched for applicable toxicity data pertinent to assigning a rank. No attempt is made to review the database or document sources as it is assumed they have already undergone peer review by experts. These databases and documents are assumed authoritative. For example, the HSDB often contains information on toxicity values that are applicable to assigning a grade for a

chemical. The HSDB sources are not reviewed, as a review would require more technical expertise than is expected for implementation of the QCAT.

Several organizations have compiled lists of chemicals of concern using these authoritative sources and these databases include many of the sources used in a Step I evaluation. Users may not need to compile a list of their own or need to decipher the information on all the individual sites but may defer to some of these compilations. Most of the files for a Step I review are available for free at the Chemical and Hazard Alternatives Toolbox, ChemHAT, created by a partnership between the IUE-CWA, the Industrial Division of the Communications Workers of America and the BlueGreen Alliance (BGA). ChemHAT does not use the GreenScreen ListTranslator® (LT®) benchmarks developed by Clean Production Action (CPA), the developer of the GS methodology. However, many of the authoritative lists used in the LT® can be found in ChemHAT, saving the assessor considerable time and effort by collecting many Step I data sources in one location.

Other sites are available that, for a fee, enable a quick evaluation of Step I resources. An automated version of the authoritative lists used in the GS®, the GreenScreen ListTranslator® (LT®), was developed through a partnership between:

- CPA.
- The Healthy Building Network, an association of environmentalists interested in healthier building products.[5]
- The Wercs, a hazard communication software platform and regulatory content provider.[6]

The LT® compares chemicals against data in authoritative lists for all 18 GS® hazard endpoints and identifies any for specific chemicals. Chemicals are separated into three categories:

1. LT-1: Chemicals that have specific hazard concerns.
2. LT-P1: Chemicals that may be an LT-1 but need further technical review.
3. LT-U: Chemicals with unknown ranking based upon the sources used.

As the LT®, QCAT and GS® all use the same authoritative lists, any chemical identified as an LT-1 would automatically equate to a QCAT Grade F and GS® Benchmark 1. The user should document the specific hazard criteria and the authoritative body making the identification in the final QCAT report. The chemical is assigned a Grade F and no further evaluation is necessary.

The Healthy Building Network developed Pharos, a database containing the hazard information found in Step I sources. Pharos creators define it as '…a partnership, pairing those who use building materials with those who study the products' impacts on health and the environment.'[7] Pharos is available only to those who pay a nominal yearly fee, currently $180 per year. Monthly or multiple options are also available. The LT® is available as part of TheWercs standard services for which a fee is charged on a monthly basis. An

[5] Healthy Building Network
[6] The Wercs Products & Services
[7] Healthy Building Network Pharos database.

assessor who has access to either database can quickly identify any hazards from Step I authoritative sources.

In addition to these two pay sites, free sites are also available. The major limitation to the free sites, however, is that they often are not updated on a regular basis and may not contain up-to-date Step I sources. Recent additions or deletions from authoritative lists may not be included. The Chemical Hazard and Alternatives Toolbox (ChemHAT) is a free source that can help an assessor conduct a QCAT analysis. ChemHAT '*…is a new internet database designed to offer up easy to use information that we can use to protect ourselves, our families and our co-workers against the harm that chemicals can cause. ChemHAT is based on the simple idea that when we know how a chemical can hurt us we can take protective action.*' The advantage to ChemHAT is that a wide range of current information is freely available to all interested parties.

As part of its implementation of the Children's Safe Product Act, Ecology compiled chemicals from authoritative sources into one specific source called High Priority Chemicals or HPCs.[8] The States of Maine[9] and Minnesota[10] generated similar lists based upon the same sources, which are also publicly available. Several other lists exist, so a user may wish to review the different compilations and decide if any would assist in their evaluation process. The Interstate Chemicals Clearinghouse (IC2) has compiled these lists into a single source. A user can search the IC2 database and find out if a chemical was identified by a specific state and what hazard criteria caused it to be placed on the state list.[11]

D. QCAT Data Gap and Grading Processes

The QCAT grading process is based upon EPA's DfE methodology and subsequent changes reflected in the CPA GS® benchmarking method. The first step in the grading process is to assign a degree of concern using all data from Step I and II sources. The data are compared to the ranking criteria established (Appendix 8) and assigned one of five rankings ranging from very high (royal purple), high (red), moderate (yellow), low (green) and very low (blue). The color coding provides a visual representation of the level of concern associated with each hazard. The ranking results can be visually displayed (Table 5):

Table 5: Example of QCAT Reporting Table

Human - Group 1					Human - Group 2							Env. Health			Fate		Physical	
C	M	R	D	E	AT	ST	N	SnS	SnR	Irs	IrE	AA	CA	Eo	P	B	Ex	F
H	M	L	vH	DG	M	X[12]	X	X	X	X	X	H	X	X	vL	vL	X	X

Each box is highlighted to show the level of concern. The same table is used to report both QCAT and GS® results. Boxes highlighted in grey and marked with an 'X' represent hazard criteria excluded from a

[8] Stone and Delistraty, Sources of toxicity and exposure information for identifying chemicals of high concern to children, Env. Imp. Assess. Review, 2009 or the Washington's CSPA Process Used to Generate Reporting List
[9] Maine Chemicals of High Concern
[10] Minnesota Toxic Free Kids Act Chemicals of High Concern
[11] IC2 State Priority Chemicals Resource
[12] Note: Boxes highlighted in grey with an 'X' are GS® criteria not included in QCAT

QCAT assessment. This presentation represents the increased risk involved with a restricted analysis like QCAT compared with a more comprehensive GS® review.

Once the levels of concern are identified, the next step is to assign a grade. QCAT grading and data gap analysis are a simplification of the GS® benchmarking and data gap processes. Any future changes to the GS® data gap and benchmarking processes will be reflected in future QCAT upgrades. An initial grade is assigned using the following decision logic (Table 6):

Table 6: QCAT Process for Assigning an Initial Grade

Grade A	1. Low P + Low T (AA, AT and all HH endpoints)
Grade B	1. Moderate P; or 2. Moderate B; or 3. Moderate AA; or 4. Moderate AT or one or more HH endpoints
Grade C	1. Moderate P + Moderate B + Moderate T (AA, AT, or any HH endpoint); or 2. High P & High B; or 3. High P + Moderate T (AA, AT, or any HH endpoint); or 4. High B + Moderate T (AA, AT, or any HH endpoint); or 5. Very High T (AA or AT)
Grade F	1. PBT = High P + High B + [Very High T (AA or AT) or High T (HH)]; or 2. vPvB = very High P + very High B; or 3. vPT = very High P + [very High T (AA or AT) or High T (HH)]; or 4. vBT = very High B + [very High T (AA or AT) or High T (HH)]; or 5. High T (HH)

Legend

AA	=	Acute Aquatic Toxicity	P	=	Persistence
AT	=	Acute Mammalian Toxicity	PBT	=	Persistent, Bioaccumulative, & Toxic
B	=	Bioaccumulation	R	=	Reproductive toxicity
C	=	Carcinogenicity	T	=	Toxic
D	=	Developmental Toxicity	vBT	=	very Bioaccumulative & Toxic
E	=	Endocrine Activity	vPT	=	very Persistent & Toxic
HH	=	Human Health (C, M/G, R, D & EA)	vPvB	=	very Persistent & very Bioaccumulative
M	=	Mutagenicity/Genotoxicity			

The grading process begins by evaluating available data against the Grade F criteria. If none of the Grade F criteria are met, the ranking results are compared against the Grade C criteria. If no Grade C criteria are met, the process continues until a grade is determined.

Once an initial grade has been assigned, the chemical must be subjected to a data gap analysis. As with the grading process itself, the data gap analysis is similar to the process established for the GS®. The data gap process reviews the data gaps found in the chemical ranking table for a specific chemical and, if necessary, reduces the grade's final grade based on the number and relative importance of the data gaps.

The following is the QCAT data gap analysis process:

Grade F: Any chemical that qualifies for a Grade F will not undergo a data gap analysis. Grade F is the lowest possible grade to which any chemical can be assigned. Therefore, any data gaps would only reinforce the assignment of a Grade F and are unnecessary. If your chemical has attained a Grade F based on existing data, continue with the review of other alternatives.

Note: The QCAT user is cautioned in placing confidence in any grade assigned above Grade F. Because QCAT uses fewer criteria and less data, the risk of incorrectly assigning any chemical a grade above F increases substantially. The QCAT user, however, may wish to proceed and use the other grades as a further prioritization tool to winnow down potential alternatives. Those chemicals that receive the best QCAT grade may be subjected to a more complete GS® analysis to increase confidence in the chemical's ability to function as a safer alternative.

Grade C: If a chemical has been assigned a Grade C, data gaps could potentially adversely affect this grading. Based on the data gaps, the following evaluations are made:

- Are there data gaps for *three or more* Human Health endpoints?
- Is there a data gap for *any of the following*: Persistence, Bioaccumulation, Acute Mammalian Toxicity or Acute Aquatic Toxicity?
- Are there data gaps for *two* Human Health endpoints, **and** are the gaps anything *other than* Endocrine Activity **and** *one of the follo*wing: Carcinogenicity, Reproductive toxicity, or Developmental toxicity?

- If the answer is 'yes' to **any** of the above questions, a **Final Grade** of $\mathbf{F_{dg}}$ is assigned.

The 'dg' indicates the chemical is assigned a Final Grade F, based on serious data gaps. It also communicates that, although the chemical is provisionally a Grade F, its grade can be revisited if data becomes available to fill in the data gap.

Grade B: If a chemical has been assigned a Grade B, data gaps could potentially adversely affect this grading. Based on the data gaps, the following evaluations are made:

1. Are there data gaps for *three or more* Human Health endpoints?
2. Is there a data gap for *any of the following*: Persistence, Bioaccumulation, Acute Mammalian Toxicity or Acute Aquatic Toxicity?

3. Are there data gaps for *two* Human Health endpoints, **and** are the gaps anything *other than* Endocrine Activity **and** *one of the follo*wing: Carcinogenicity, Reproductive toxicity, or Developmental toxicity?
4. Are there data gaps for any Human Health endpoints *other than* Endocrine activity?

- If the answer is 'yes' to **any** of Questions 1, 2 or 3, a **Final Grade** of $\mathbf{F_{dg}}$ is assigned.
- If the answer is 'yes' to Question 4, a **Final Grade** of $\mathbf{C_{dg}}$ is assigned.

The 'dg' indicates the chemical is assigned a Grade C, based upon serious data gaps. This communicates to the manufacturer that, although initially a Grade B, the final grade was adjusted, based upon the data gaps. The final grade can be revisited once data are available to fill in data gaps.

Grade A: If a chemical has been assigned a Grade A, data gaps could potentially adversely affect this grading. Based upon data gaps, the following evaluations must be made:

1. Are there data gaps for *three or more* Human Health endpoints?
2. Is there a data gap for *any of the following*: Persistence, Bioaccumulation, Acute Mammalian Toxicity or Acute Aquatic Toxicity?
3. Are there data gaps for *two* Human Health endpoints, **and** are the gaps anything *other than* Endocrine Activity **and** *one of the follo*wing: Carcinogenicity, Reproductive toxicity, or Developmental toxicity?
4. Are there data gaps for any Human Health endpoints *other than* Endocrine activity?
5. Is there a *data gap for Endocrine Activity*?

- If the answer is 'yes' to **any** of Questions 1, 2 or 3, a **Final Grade** of $\mathbf{F_{dg}}$ is assigned.
- If the answer is 'yes' to Question 4, a **Final Grade** of $\mathbf{C_{dg}}$ is assigned.
- If the answer is 'yes' to Question 5, a **Final Grade** of $\mathbf{B_{dg}}$ is assigned.

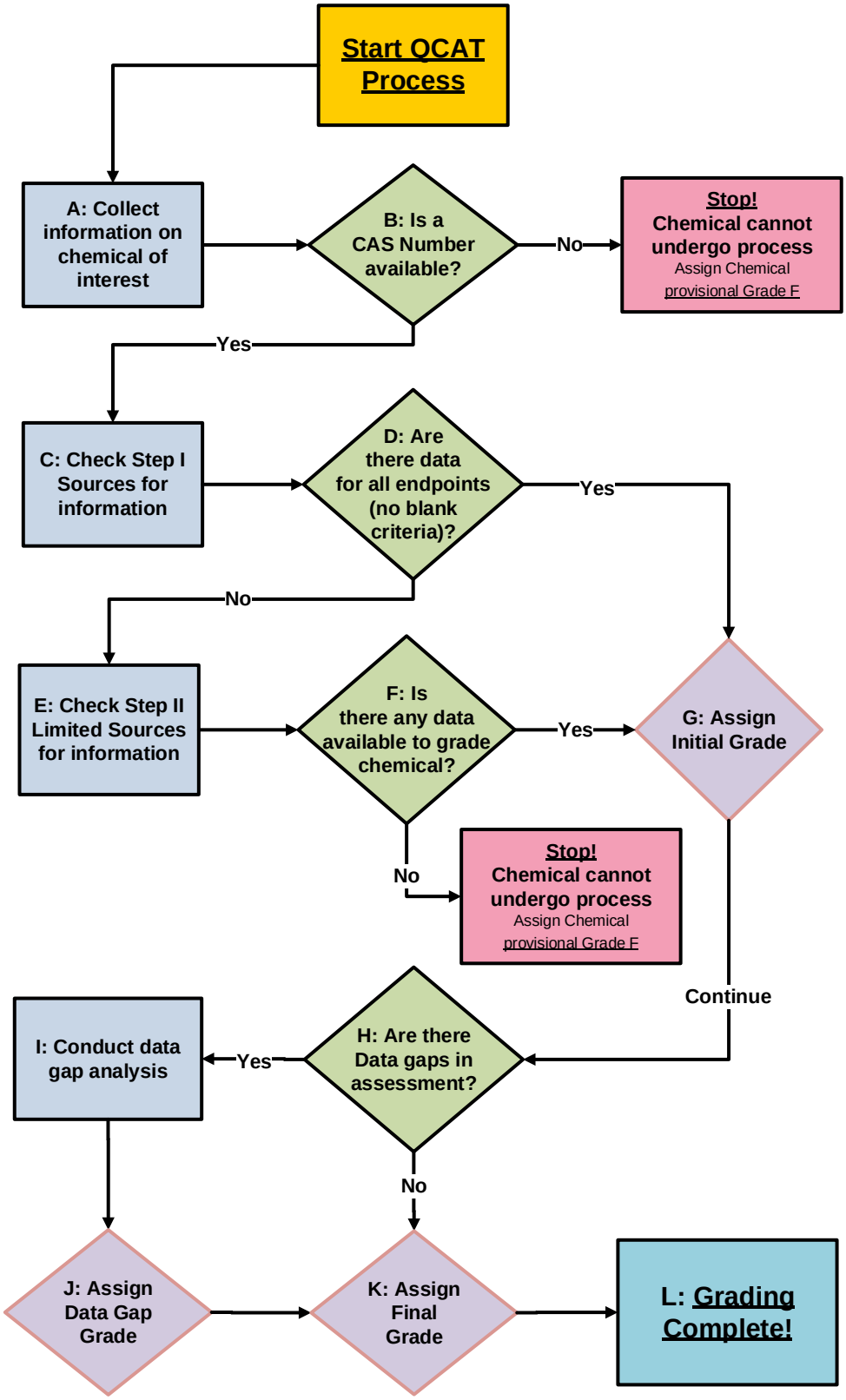
The 'dg' indicates the chemical is assigned a Grade B, based upon a data gap. This communicates to the manufacturer that, although its chemical is initially assigned a Grade A, the final grade must be adjusted, based upon the importance of the data gaps. The final grade can be revisited once data are available to fill in data gaps.

As observed above, no chemical using the QCAT methodology can be assigned a Grade A if any data are missing. Just because a chemical has obtained a high grade using QCAT, a further review should be completed using a full GS® analysis to be sure any of the missing criteria do not adversely affect its grade.

4. QCAT Decision Logic

The QCAT decision logic and evaluation process are shown in Figure 1:

Figure 1: QCAT Decision Logic



E. Results from the QCAT Grading Processes

Once the evaluation is complete for all the chemicals undergoing the QCAT review, the potential risks associated with each chemical can be compared directly. Those chemicals assigned Grade F should be removed from the manufacturing process. Safer alternatives should be sought for chemicals with a Grade C, although they can be used while the search begins. Grade B chemicals still have some room for improvement but they are closer to being 'green.' Grade A chemicals are protective of human health and the environment, based upon the QCAT review. A manufacturer may wish to subject these chemicals to a GS® analysis to make sure that no unidentified hazard concerns exist. However, compared to other chemicals, Grade A chemicals do not pose a substantial risk for the priority endpoints used in the QCAT analysis.

The QCAT decision logic is based on seven decision points that enable a user to complete the grading process. Before each decision point, data are collected to assist the user in making the subsequent decision. Each decision point will be assigned a number and is described below with the data collection requirements preceding the decision point.

The same method should be used to report results from the QCAT assessment as used for the GS® analysis. An example of a sample matrix is found in Appendix 3. Those hazard endpoints used in the GS® but omitted from QCAT are shaded grey and contain an 'X'. In this manner, it is clear the results from the QCAT lack analysis of certain hazard endpoints used in the GS® and that, without this data, the uncertainty associated with the QCAT conclusions is greater.

5. Start QCAT Process

A. Collect Information on Chemical of Interest

To begin the evaluation process, collect some basic information on each chemical:

- Chemical name
- CAS number

If additional information is available, it may be advantageous to include it at this point. Other information of interest includes, but is not limited to:

- Octanol/water coefficient (typically displayed as log K_{ow})
- Potential degradation products
- Uses

B. Is a CAS Number Available?

A CAS number must be identified for each chemical to undergo the QCAT process. Without a CAS number, pertinent human health and environmental hazard data cannot be identified; therefore, a chemical without a CAS number automatically exits the process and is assigned a provisional Grade F (CAS). This assessment may change as manufacturers provide more information or EPA alters its interpretation of confidential business information.

C. Check Step I Data Sources for QCAT Hazard Endpoints

Appendix 1 identifies sources used in Step I for implementation of the QCAT. In Step I, the authoritative lists are evaluated to determine if any of the chemicals undergoing evaluation appear on these authoritative sources. As indicated previously, two pay sites and several states and organizations have established lists of chemicals of concern that include many of the sources indicated in Step I. A user may wish to investigate these lists to see if any can be used in lieu of researching each individual source. See Appendix 1 for more details on these lists.

The sources in Step I are primarily authoritative lists and the evaluation depends on whether or not a chemical appears on the list. Some lists also provide information on the relative level of concern for the chemical, based upon available data and review by technical experts. For example, EPA's Integrated Risk Information System (IRIS) database using 1986 criteria identifies chemicals as known, probable, and possible carcinogens. Include these details in the assessment results, as they will assist in the grading process.

Four simple databases have also been included in Step I sources. Information is provided at the end of Appendix 1 on how a user may access data from these databases and what data should be recorded for the grading process. At this point, all available information from the authoritative sources will be entered into the chemical matrix for each chemical.

D. Are There Data for all Hazard Endpoints?

Once a table has been filled in with appropriate data from Step I sources (see Table 5 for an example table), assessors determine if data have been found for all QCAT hazard endpoints. Hazard endpoints identified in Step I data sources will not be evaluated further. Presence in any Step I source is deemed authoritative. **Only those chemicals that do not appear in Step I sources will be subjected to further Step II review**. There is sufficient information to assign a final grade and the grading process jumps to decision #4.

E. Check Step II Data Sources for QCAT Hazard Endpoints

If any QCAT hazard endpoints remain blank after reviewing the data from Step I, research further for additional information using Step II data sources. Additional Step II data sources are identified in Appendix 2. The user should **look only for data to fill in any remaining gaps**. For example, if information was found in Step I sources for carcinogenicity, there is no need for information in Step II sources. The sources used in Step I are deemed authoritative and can be used directly in the grading process without further review or need for additional information.

Several databases in Step II assist in assigning a hazard level to any remaining hazard endpoints. Guidance is provided at the end of Appendix 2 on how a user may access information in each database and what data should be recorded for the grading process.

The user should attempt to locate data from at least two Step II sources before ranking the chemical. If only one data source is found, the chemical can still be ranked using the information; however, the QCAT report should indicate that further review might be warranted based upon the limited information available.

If after checking all Step I and II data sources, information has not been found for one or more of the QCAT hazard endpoints, enter a 'DG' for 'data gap' into the matrix for that hazard endpoint(s). 'DG' indicates that, although all data sources were evaluated, no data have been found to assign a rank for this chemical for this specific hazard endpoint.

F. Is There Data for any Hazard Endpoints That Can be Used to Grade the Chemical?

Once the table has been filled in with appropriate data from Steps I and II sources and any data gaps have been identified, determine if data have been found for one or more of the hazard endpoints. If data are found for one or more of the nine hazard endpoints, assess the data and begin the grading process identified in #4.

If no data have been found using Step I and II sources, and only data gaps appear for all QCAT hazard endpoints, the chemical automatically exits the evaluation and is assigned a provisional grade 'F.' No further evaluation of this chemical occurs. Within the constraints of the QCAT system, this chemical is not a viable alternative to the toxic chemical being replaced. While data may exist for this chemical in sources not used by the QCAT, and may identify this chemical as a viable alternative, this more detailed review is outside the scope of the QCAT.

G. Assign an Initial Grade to the Chemical

First, determine the level of concern for each hazard endpoint using the data collected from the Step I and II sources. The level of concern ranges from very low to very high and are color coded: very high (royal purple), high (red), moderate (yellow), low (light green) very low (blue). Such color-coding aligns with the GS® and DfE and assists in assigning an initial grade to the chemical.

The relative ranks are identified using the process explained in Appendix 8. The result is a matrix with ranks filled in for all endpoints (Table 7). The QCAT assessor should use this approach to display final results. As in the matrix used by DfE and GS®, it demonstrates the QCAT assessment is based on fewer hazard endpoints and therefore less exacting than a full DfE and GS® assessment.

Table 7: Example of Assigned Level of Concern for Each Hazard Endpoint

Human - Group 1					Human - Group 2							Env. Health			Fate		Physical	
C	M	R	D	E	AT	ST	N	SnS	SnR	Irs	IrE	AA	CA	Eo	P	B	Ex	F
H	**M**	**H**	**H**	DG	vH	X	X	X	X	X	X	H	X	X	L	vL	X	X

Once the levels of concern have been assigned for each hazard endpoint with available data, an initial grade is assigned. This is accomplished using the process described in Table 6. The result of this evaluation will assign an 'Initial Grade' as shown in Table 8.

Table 8: Example of an Initial Grade Assigned Based Upon the Levels of Concern Identified

Initial Grade	**F**

Data gaps are ignored at this point and a grade is assigned, based solely on what information is available. A further evaluation will evaluate any data gaps to determine what level of confidence can be assigned to augment the initial grade.

H. Are There Missing Data for any Hazard Endpoints?

To better coordinate data requirements with existing regulatory requirements, a process has been established in the GS™ to evaluate chemicals for data gaps in important hazard endpoints. This process has been incorporated into the QCAT method. If 'DG' is found for one or more of the hazard endpoints, a further assessment is required.

I. Conduct a Data Gap Analysis

Essentially, if a chemical undergoing the QCAT evaluation is missing data for one or more of the QCAT hazard endpoints, the impact these gaps may have on the initial grade assigned using available data is assessed.

The ideal scenario would be to find data to assign a hazard level for each hazard endpoint. In reality there are chemicals for which no data is available for one or more hazard endpoints, and/or for which the chemical manufacturer is withholding data as confidential business information.

The GS® methodology Version 1.2 includes a data gap analysis. The intention of the data gap analysis and subsequent scoring is to promote and incentivize generation and disclosure of chemical hazard data. When data are missing and the hazard level for one or more hazard endpoints is unknown, caution is used when benchmarking the chemical. More complete data sets are required to achieve each subsequent benchmark score (from red to green).

In essence, the data gap analysis attempts to quantify the confidence in the initial grade assigned to each chemical. If data exists for all the hazard endpoints, the confidence is high that the impacts to human health and the environment can be correctly assessed. If there are important data gaps, the confidence in the assessment decreases substantially. The QCAT is guided by the most current version of the GS® data gap analysis.

J. Assign a Data Gap Grade to the Chemical

The QCAT data gap process is very straightforward and is explained in more detail in the previous section 'Conduct a Data Gap Analysis'. If a chemical is assigned an initial grade F based upon the data found, no data gap analysis is necessary, as data gaps will not adversely impact the assessment. If, however, a chemical is assigned any grade higher than an F, the data gap analysis will attempt to quantify how confident we are in the assessment. Based upon the data gap analysis, a second 'final'' grade is assigned. The chemical has now been assigned two grades, a grade based upon the data found (Initial Grade) and a second based upon data gap analysis (Final Grade).

K. Assign a Final Grade

The assessor has identified two grades, the Initial Grade based upon data found and the Data Gap Grade based upon the number and importance of any data gaps. Based upon these two grades, the chemical is assigned a Final Grade by selecting the lower of the two previous grades.

L. Grading Complete!

Congratulations! You have successfully completed the QCAT process. You can now summarize the grades assigned to all of the chemicals you have assessed using the QCAT. As part of the QCAT process, summarize the results of a QCAT evaluation for each chemical evaluated into a standardized format as shown in Appendix 6. The standardized format is based on a similar report used to report the results from a GS® evaluation. The details of the evaluation are documented and available for sharing with other interested parties. An example of a completed format for a QCAT evaluation is shown in Appendix 7.

It is important to understand how to interpret the grades. A chemical could receive a very high grade, based on what is known about it. However, if data on important priority endpoints are missing, there is less confidence that this grade actually reflects the potential impact the chemical may have on human health and the environment.

Table 9 demonstrates these principles with a real life example. Ecology evaluated several chlorinated solvents against four fluorinated compounds that were being sold as safer alternatives. The two compounds listed in Table 9 appear to have the lowest impact on human health and the environment. Although the fluorinated compound received a better initial grade (B versus C for the chlorinated compound), uncertainty about the Grade B is greater because data for an important hazard endpoint (acute aquatic toxicity) is missing. The fluorinated compound's initial grade has greater uncertainty, as this chemical has unknown toxicity to the environment and the grade is reduced to F_{dg} to represent this greater uncertainty.

Although the chlorinated species received a lower grade 'C,' data for all of the six priority endpoints are present for the chlorinated species. Only endocrine activity and carcinogenicity data are missing. The chlorinated species have data for mutagenicity/genotoxicity, which can give an indication of whether these chemicals may be carcinogenic. Thus, the lack of a carcinogenicity study for the chlorinated species is not considered fatal to the evaluation and the grade after considering data gaps remains at 'C.'

Table 9: Example of Two Halogenated Solvents

	Human - Group 1					Human - Group 2							Eco			Fate		Physical	
	C	M	R	D	E	AT	ST	N	SnS	SnR	Irs	IrE	AA	CA	Eo	P	B	Ex	F
Chlorinated	DG	L	L	L	DG	M	X	X	X	X	X	X	M	X	X	vH	vL	X	X
Fluorinated	L	L	L	L	DG	L	X	X	X	X	X	X	DG	X	X	vH	vL	X	X

	Grades		
	Initial	Data Gap	Final
Chlorinated	C	C	C
Fluorinated	B	F_{dg}	F_{dg}

The QCAT does allow incremental improvements, which may be necessary until data for all hazard endpoints become available. For example, you have two chemicals that have obtained Grades B and C respectively, based upon available data. However, after the data gap analysis, the chlorinated compound received a Grade C and the fluorinated compound a Grade F_{dg} due to data gaps.

If a decision was made between these two chemicals based upon the initial Grade, the fluorinated compound would be considered a safer choice, i.e., select the chemical with a B grade over the one with a Grade C. However, upon further data gaps review, very important information is missing for the fluorinated compound and selection of the fluorinated alternative is actually risky due to the lack of important data. The user may wish to contract with a toxicological service to conduct a more detailed GS® assessment. Without additional data, a clear choice cannot be made between the two options. The final user would decide which chemical to use or, perhaps more appropriately, explore whether other alternatives are more well-defined and have less of an impact upon human health and the environment. Until data on all the QCAT endpoints are available, however, the risk of making a choice about a chemical with unknown hazards cannot be evaluated. Thus, data gaps are important in the evaluation process.

References

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Clean Production Action (CPA), 2007. The GreenScreen™ For Safer Chemicals: Evaluating Flame Retardants for TV Enclosures, 82 pages.

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Green Chemistry & Commerce Council (GC3), 2012. Business and Academic Partnerships for Safer Chemicals.

Interstate Chemicals Clearinghouse (IC2), 2014. IC2 Alternatives Assessment Guide, 176 pages.

Lavoie, Emma, Lauren G. Heine, Helen Holder, Mark S. Rossi, Robert E. Lee II, Emily A. Connor, Melanie A Vrabel, David M. DiFiore and Clive L. Davies, 2010. Chemical Alternatives Assessment: Enabling Substitution to Safer Chemicals, 33, pages 924-9249.

U.S. EPA Design for the Environment (DfE), 2011. Design for the Environment Program Alternatives Assessment Criteria for Hazard Evaluation, Version 2.0, 50 pages.

DfE, 2012. Design for the Environment-An EPA Partnership Program.

University of California-Berkeley (Berkeley), 2010. Preventing Toxic Exposures-Workplace Lessons in Safer Alternatives, Joan Lichterman, Holly Brown-Williams, Linda Delp, Margaret Quinn and Julia Quint authors, Vol. 5, No. 1.

Washington State Department of Ecology (Ecology), 2006. Washington State Polybrominated Diphenyl Ether (PBDE) Chemical Action Plan: Final Plan, 307 pages.

Ecology, 2009. Alternatives to Deca-BDE in Televisions and Computers and Residential Upholstered Furniture, 118 pages.

Yamada S, 1964. An occurrence of polyneuritis by n-hexane in the polyethylene laminating plants. Jpn J Ind Health, vol. 6, p.192.

Appendix 1: Step I Data Sources

Individual Databases:

As mentioned previously, internet resources are available that accumulate information from many of the Step I lists into a single site. These sites may make a Step I evaluation easier for QCAT users. Detailed information on how to access each of these sites and obtain data that can be used in a QCAT evaluation can be found later in this appendix. The four sites of potential interest to QCAT users are:

1. The IUE-CWA, the Industrial Division of the Communications Workers of America's and the BlueGreen Alliance (BGA)'s Chemical and Hazard Alternatives Toolbox, ChemHAT.
2. Healthy Building Network's Pharos Database's Chemical and Material Library.
3. The Wercs Green Chemistry Scoring ListTranslator® (LT®).
4. The Interstate Chemicals Clearinghouse (IC2) State Priority Chemicals Resource database. The sources used to create these lists are Phase 1 authoritative sources.

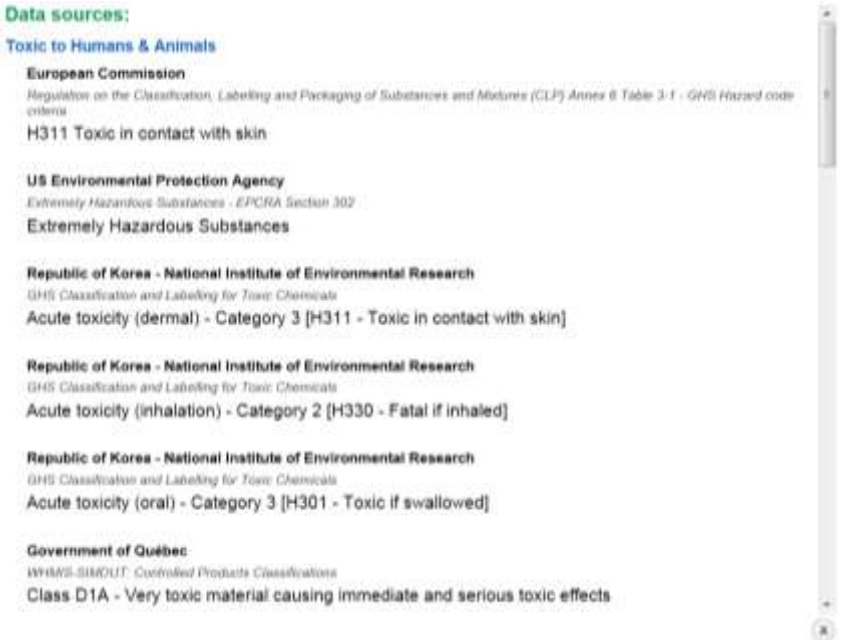
Users should check when the information on these websites was last updated. Any site that is several years out-of-date should be used with caution. However, if a chemical was identified as a problem in one of the lists included in these sites, the chemical should be avoided and removed as a potential safer alternative.

ChemHAT (Chemical and Hazard Alternatives Toolbox):

ChemHAT is a free site created by the Industrial Division of the Communications Workers of America and the BlueGreen Alliance (BGA). ChemHAT provides recommendations and identifies concerns for specific chemicals within its database. However, the data used for these recommendations are most of the same lists used in a Step I QCAT assessment. As ChemHAT is freely available to all users, it is a great source of authoritative lists and saves the assessor considerable time by providing most of the lists in one locate. Assessors can access ChemHAT through its main page:

The assessor can enter either the chemical name or the CAS number for the chemical of interest. The formaldehyde CAS number, 50-00-0, is used to demonstrate the availability of information within ChemHAT. Once the assessor clicks on the 'Find' button, the following page appears:

ChemHAT displaces information on how the chemical can affect health. In the above screen capture, acute and chronic concerns are identified. If the assessor clicks on the blue highlighted information 'How do we know' in the Acute (Short Term) Effects category (red arrow above), the following information appears:

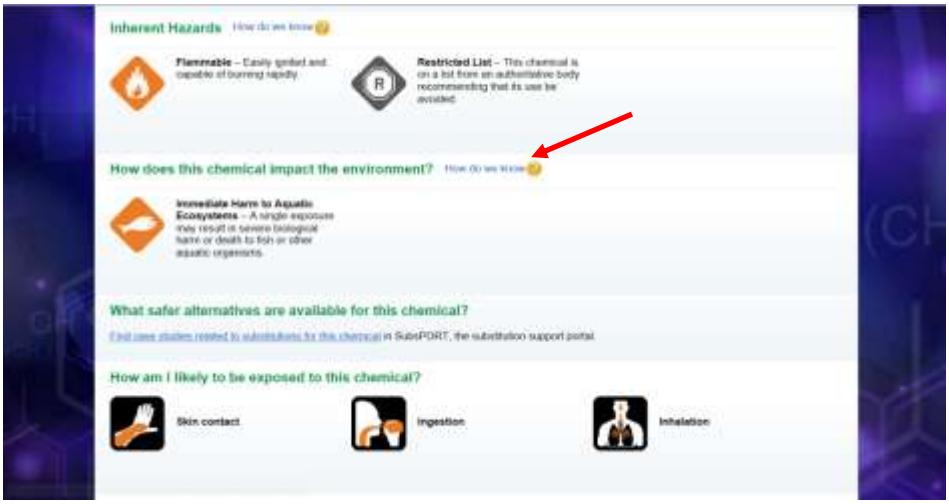


The sources identified above are Step I data sources and the data would be used to help identify the level of acute toxicity concerns associated with formaldehyde. This window can be closed by clicking on the 'x' in the lower right corner.

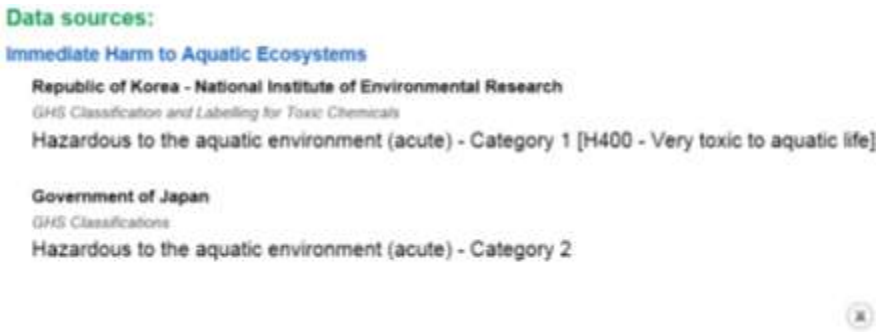
Similar data is available for chronic concerns associated with formaldehyde:

This data indicates formaldehyde is a carcinogen and the specific data results can be used in QCAT to identify a level of concern. By using this single source, however, assessors can obtain carcinogenicity data from multiple authoritative sources without the need to visit each source individually.

If the assessor scrolls further down the initial results page for formaldehyde, the following information appears and data is available on formaldehyde's aquatic toxicity (red arrow):



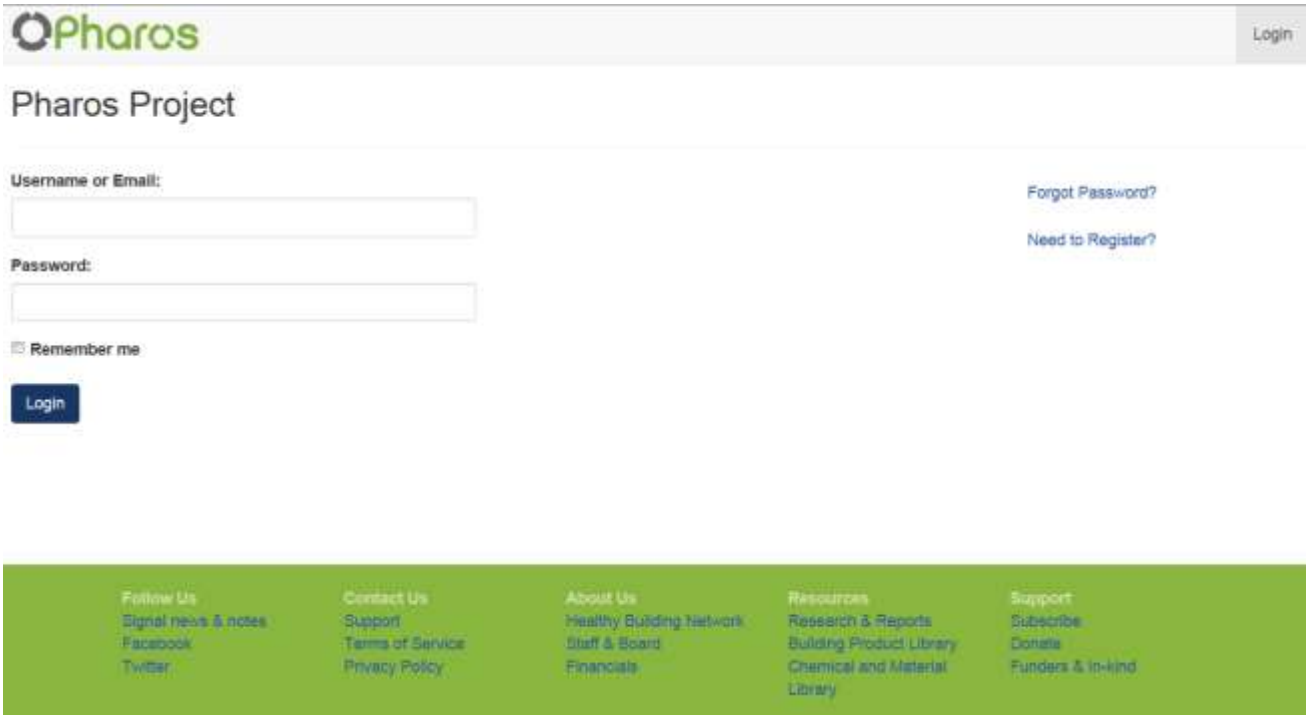
By clicking on the 'How do we know' link, the following window appears:



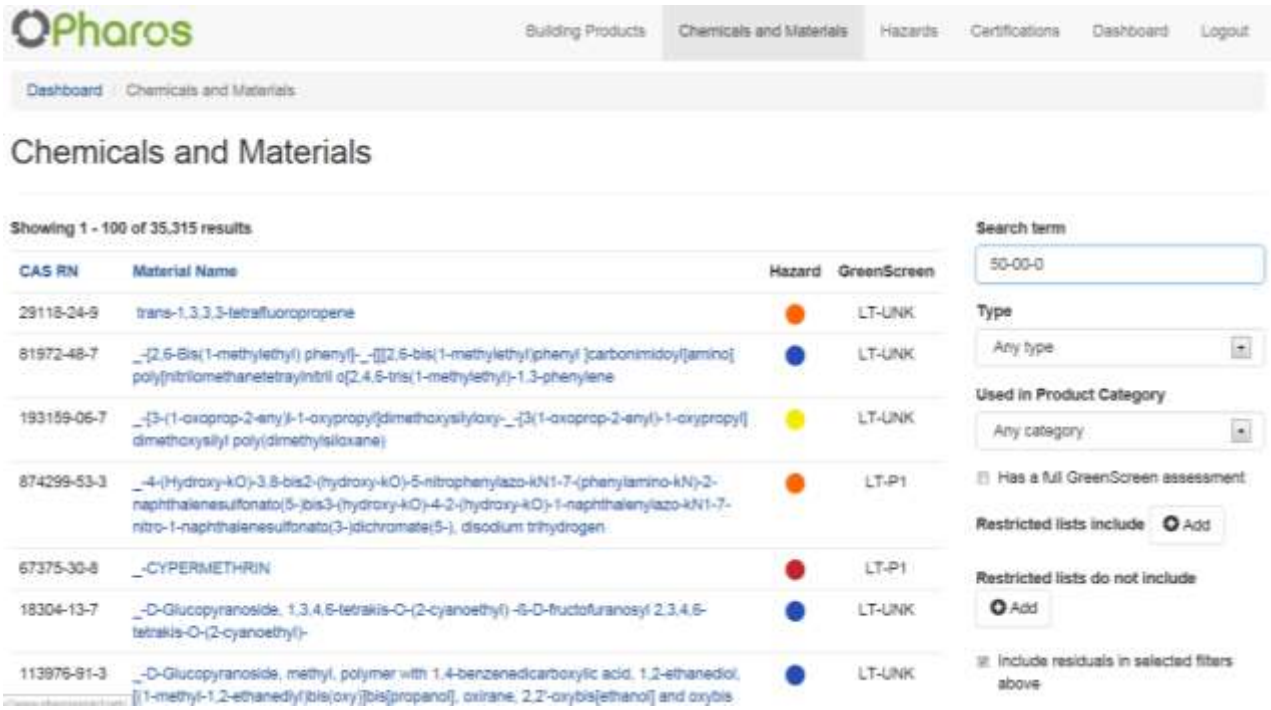
Information from ChemHAT can be used to assign a level of concern. For example, based upon the information displayed for formaldehyde, it would receive a Grade F based upon the high degree of carcinogenicity. Assessors should make the effort, however, to fill in as many of the hazard endpoints as possible. Although ChemHAT contains most of the Step I authoritative sources, it may not contain all and some of the other, more complete sources listed below should also be reviewed.

Healthy Building Network's Pharos Database:

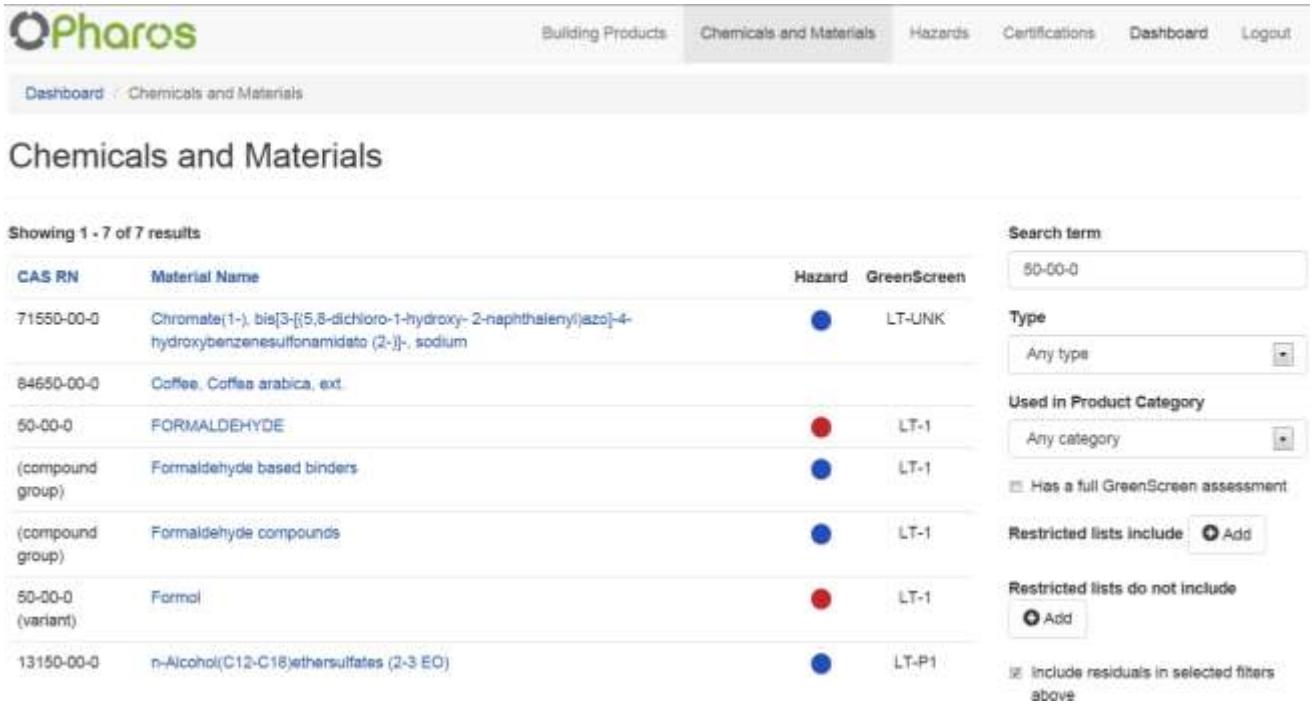
Pharos is a subscription site and may not be available to all users. Costs for access, however, are reasonable and access to the information in Pharos might justify the expense. Although Pharos was created primarily to improve the quality of building products, the data in its Chemical and Material Library is useful to QCAT users. Users login to Pharos through its main page:



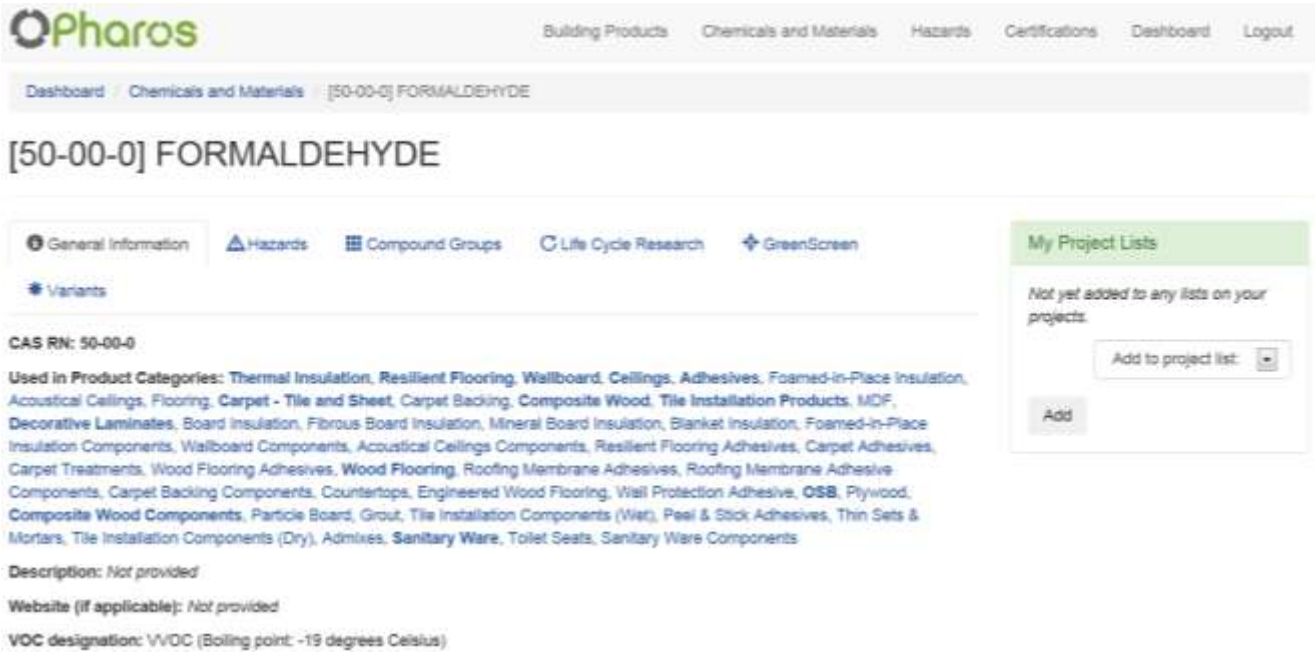
Once the assessor logs in and accesses the site, the following page appears:



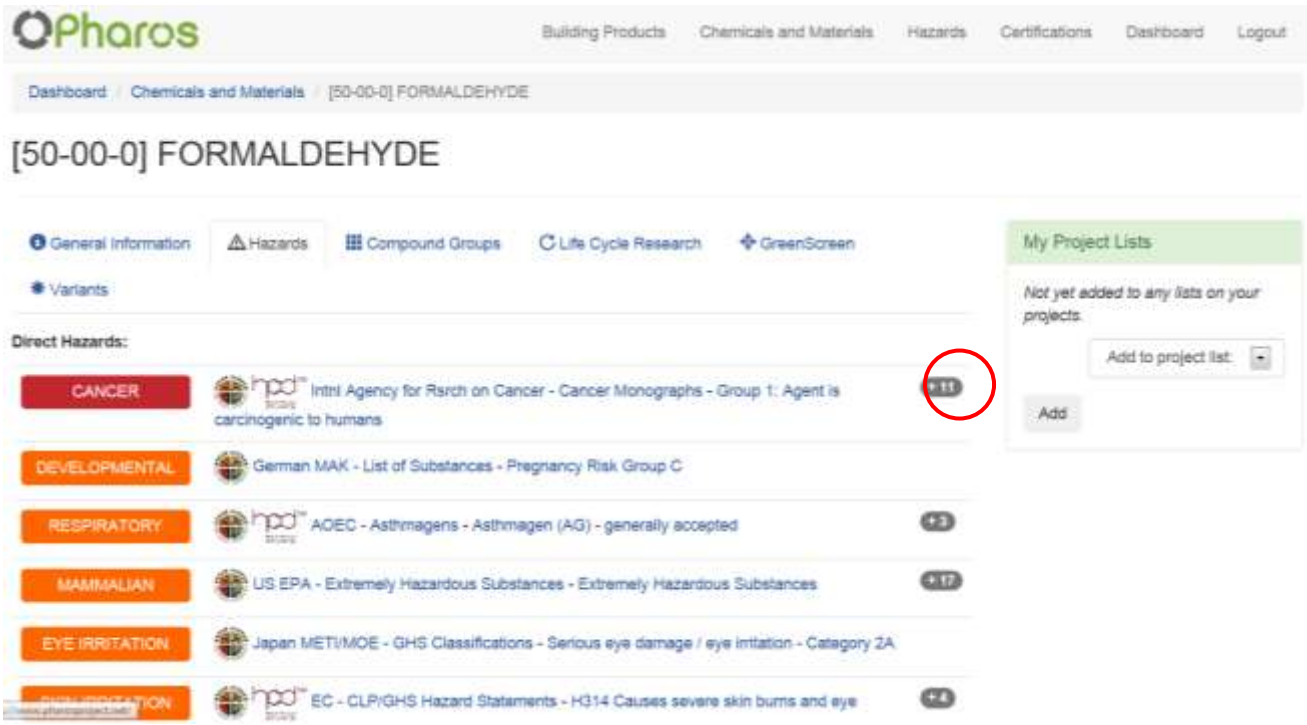
Typing ’50-00-00’, CAS number formaldehyde as an example in the box labeled ‘Search term’ and hitting ‘Enter’ leads the database to list all entries with ’50-00-0’ in the CAS:



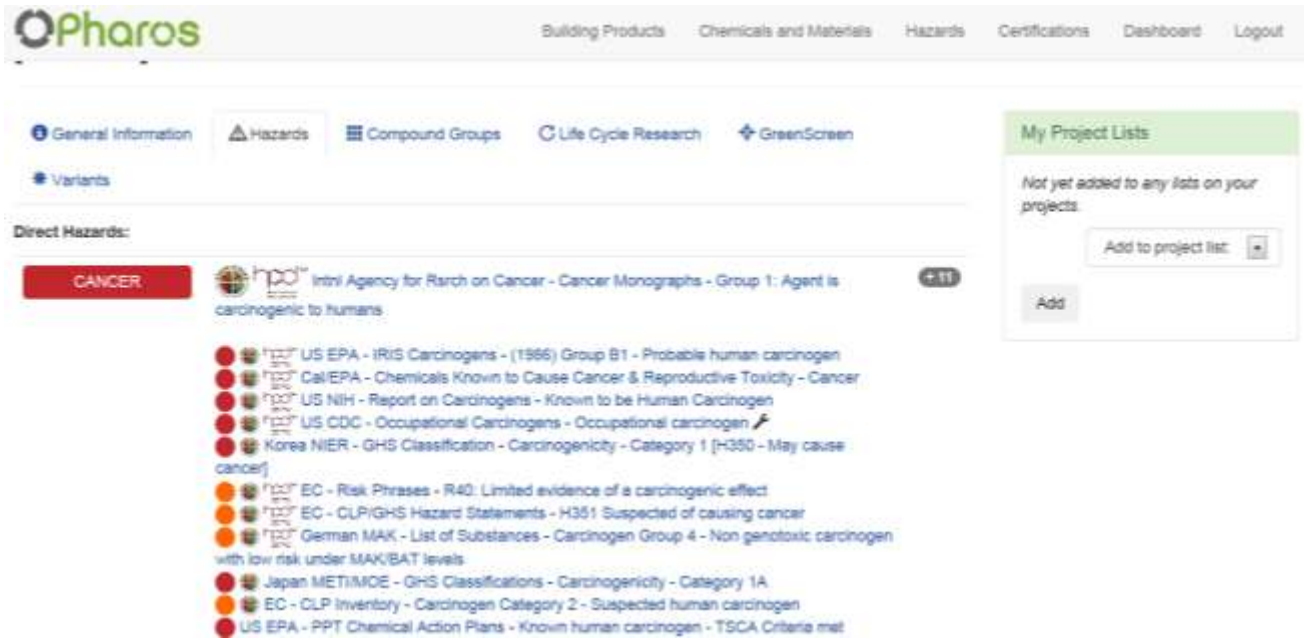
Clicking on ‘FORMALDEHYDE’ leads to the following:



This page is introductory and provides some information on uses of the chemical. Clicking on the 'Hazards' tab along the top provides access to all the hazard data on formaldehyde:



Pharos is a certified GreenScreen ListTranslator® and the colors shown agree with the level of concern identified in GreenScreen® and used in QCAT. Therefore any hazard endpoint in red is likely to be a higher level of concern than those in orange. Pharos lists one source for each endpoint and identifies additional sources available. The '+11' after 'Cancer' (circled in red) indicates there are an additional 11 authoritative sources that reviewed and provided an opinion on cancer. This information is accessed by clicking on the '+11' and the following appears:



Pharos includes information on several hazard criteria. However, the only one pertinent to a Step I QCAT formaldehyde assessment is 'CANCER' as indicated by the red color. Note the colors used in Pharos align with the color-coding used in QCAT and GS®. Pharos indicates that formaldehyde is a 'Group 1: Agent is carcinogenic to humans' as identified by the 'Intnl Agency for Rsrch on Cancer' or IARC. This indicates formaldehyde is an 'LT-1' for ListTranslator category 1, which is equivalent to a GS® Benchmark 1 or QCAT Grade F.

All information available in Pharos on the cancer hazard endpoint is shown. The information pertinent to a QCAT assessment includes:

1. Group 1: Carcinogenic to humans (IARC)
2. Known to be a human carcinogen (NTP RoC)
3. Group B1 using 1986 Guidelines (IRIS)
4. Carcinogenic (Prop 65)
5. Carcinogen (OSHA)
6. GHS Carcinogenicity Category 1, H350 May cause cancer (Korea NIER)
7. GHS Carcinogenicity Category 1A (Japan METI/MOE)
8. Known human carcinogen (US EPA)

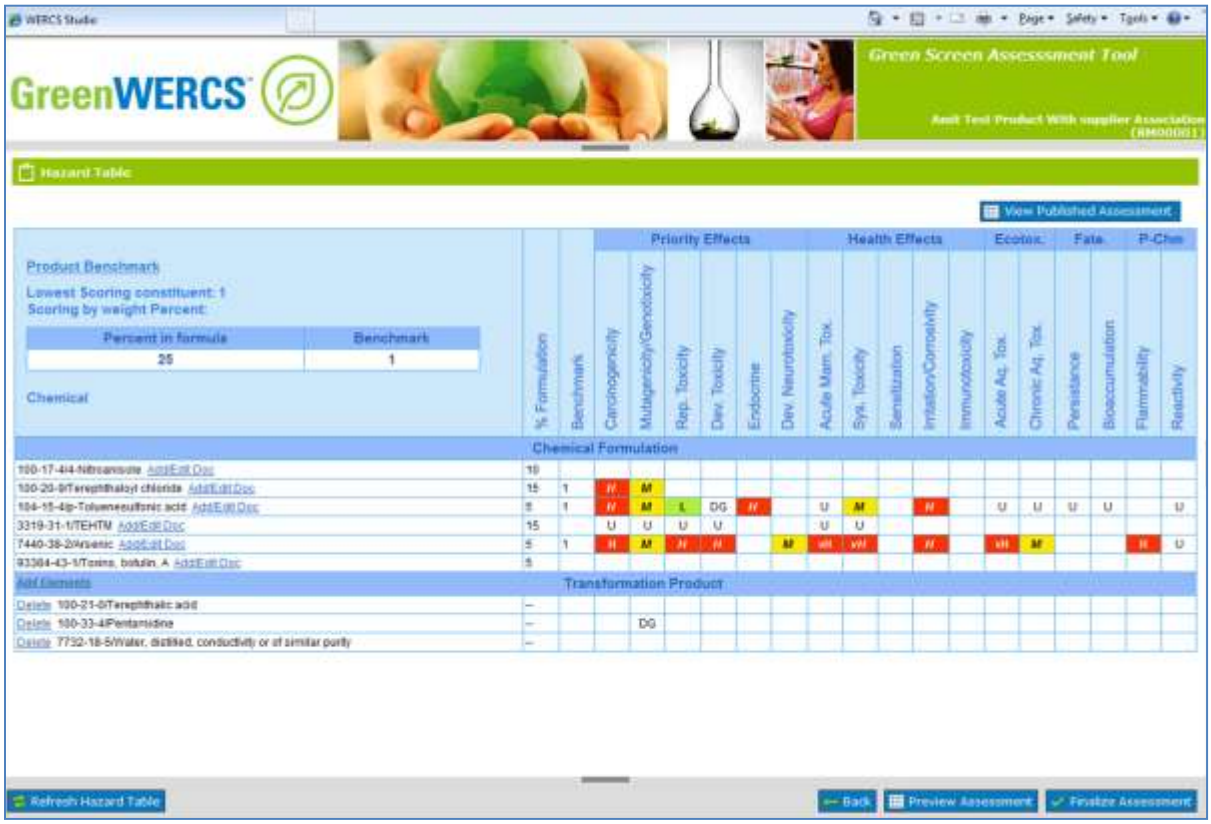
This data can be used to identify the level of concern for carcinogenicity. According to the information in Appendix 8, this information causes cancer and needs to be assigned a level of 'H.' The QCAT user should note this information in the assessment for formaldehyde and indicate where the information was obtained, i.e., the Pharos database accessed on a specific date.

Note that Pharos includes data from sources used in the GS® but not in QCAT. This information is meaningful to its target audience, i.e., suppliers of building materials. Although it is tempting to include

this information in a QCAT assessment, it is beyond the QCAT's scope and should be reserved for a GS® assessment.

The Wercs GreenWERCS:

The Wercs includes an LT® equivalent in their GreenWERCS software package. GreenWERCS users can enter their products into GreenWERCS system and select an LT® review. A table appears summarizing results for each chemical in the product similar to what is found in the QCAT and GS® methods. The chemical will also be assigned a benchmark based upon the data and using the LT ranking system. The following is an example of a GreenWERCS LT® report:

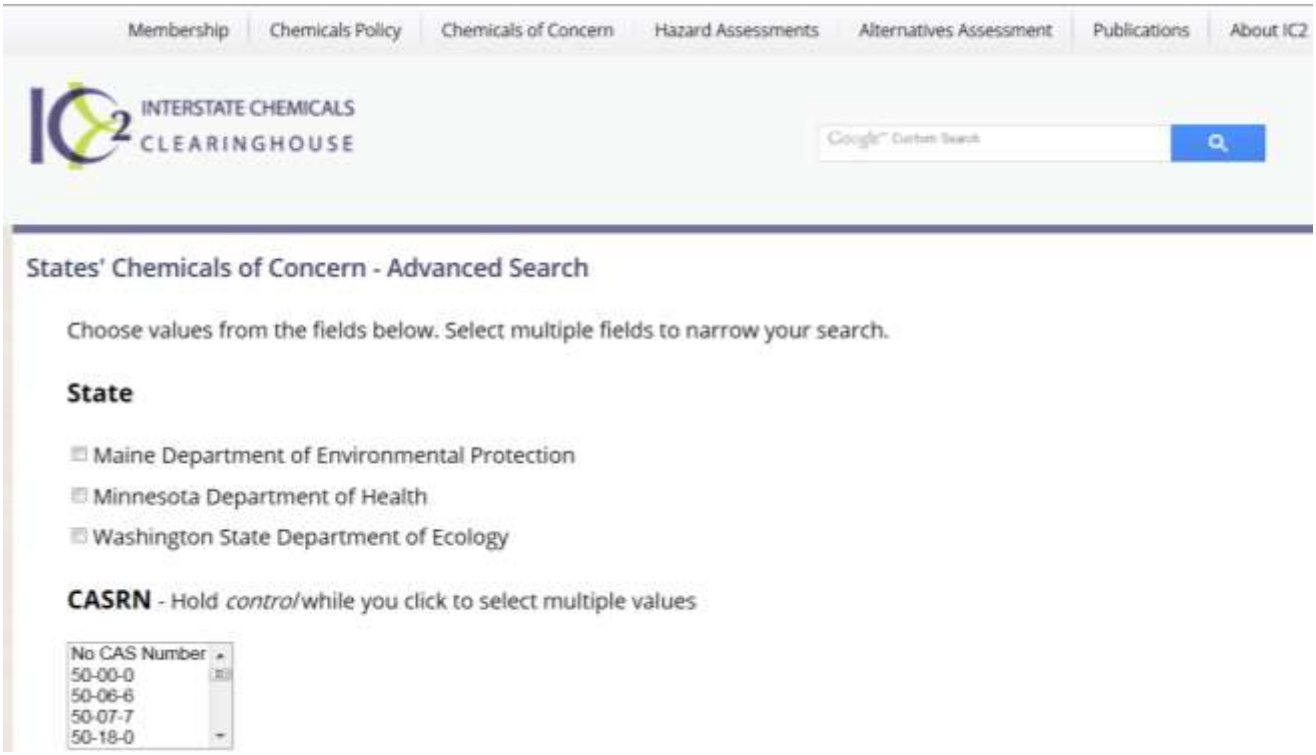


Note that the GreenWERCS uses the same table reporting format as QCAT and the GS®. Any questions about the final version should be directed to The Wercs, which can be found on the internet at: www.thewercs.com/applications/green-chemistry-scoring.

Potential users should be reminded, however, that there is a subscription cost to access The Wercs services and the information above may only be useful to users who have already paid for The Wercs.

The Interstate Chemicals Clearinghouse (IC2) Database:

The IC2 assembled data is used by three states (ME, MN, and WA) to identify chemicals of concern. These lists were created as part of a response to legislation passed in each state to identify chemicals of concern to children, a subset of society specifically vulnerable to chemicals and their impact on human health and development. This information is available to anyone interested in the sources of the chemicals identified by each state and may be useful to the QCAT users. Initial access to the IC2 Database appears as:



The QCAT user should identify the date the database was last modified. Care should be taken though that the date agrees with the last time the *data sources* were also updated in the database. The IC2 database allows users to either search for specific chemicals or to browse individual state lists. The QCAT user can search the database either by CAS number or name and can limit the search to either specific state lists or source lists:

You can also search by CAS Registry Number (CASRN) using the text box below. Separate multiple numbers with commas:

Chemical Name - Enter part or all of a chemical's name

Source List - To search a source list that includes multiple sub-lists, you must keep all sub-list check boxes selected. Selecting the source list check box and removing the sub-list check boxes will return no chemical records.

For more information, this list of sources provides descriptions of these lists and links to the organizations that developed them. [PDF].

- California's Proposition 65 Program
- Canadian Environmental Protection Act Domestic Substances List - Persistent, Bioaccumulative, and Inherently Toxic Chemicals
- EPA Integrated Risk Information System
- EPA National Waste Minimization Program - Priority Chemicals
- EPA Persistent, Bioaccumulative, and Toxic (PBT) Chemicals Program - Priority PBT Chemicals
- EPA Toxics Release Inventory Program - Persistent, Bioaccumulative, and Toxic (PBT) Chemicals
- EPA Voluntary Children's Chemical Exposure Program
- European Commission - Directive on Dangerous Substances
- European Commission - Existing Substances Registration List
- European Commission Endocrine Disruptors

An example search based upon the CAS number for formaldehyde (50-00-0) and the three state lists (checked) appears as:

Search Results

1 record returned - search within these results

Search Criteria: Show

Formaldehyde (50-00-0)

States listing this chemical: ME DEP, MN DOH, WA DOE

Lists referencing this chemical:

- California's Proposition 65 Program - Carcinogens
- EPA Integrated Risk Information System Carcinogens - 1986 criteria
- International Agency for Research of Cancer - Known carcinogens
- National Toxicology Program - 11th Report on Carcinogens - Category B reasonably anticipated carcinogens

This information is similar to what was found in other databases although additional information is provided as well. The information pertinent to a QCAT assessment includes:

1. Carcinogen (Prop 65)
2. Carcinogen (EPA IRIS)
3. Known Carcinogen (IARC)
4. Category B 'reasonably anticipated carcinogen' (NTP)

This data can be used to assign a carcinogenicity rank for formaldehyde. The QCAT user should note the source and date this information was obtained and proceed with the QCAT assessment.

Step I Authoritative Lists:

Authoritative lists for the endpoints identified in Table 3 are provided below. Few authoritative government lists currently exist for neurotoxicants, acute aquatic toxicity, vPTs and vBTs, and endocrine disruptors. Authoritative lists are based on evaluation of only a limited set of the approximately 80,000 chemicals in commerce. Many chemicals have simply not been tested. The authoritative lists that follow provide a starting point for identifying chemicals of high concern. For the QCAT, information will be selected from specific lists and from a few, easily accessible databases, which require no interpretative requirements. Information from these specialized databases will be described at the end of this appendix.

Human Health: Carcinogenicity

1. U.S. National Institutes of Health, National Institute of Environmental Health Sciences, National Toxicology Program (NTP), 12th Report on Carcinogens (ROC).

   NTP creates lists of chemicals that have been reviewed for carcinogenic impact. The following categories are used in QCAT:
   a. Known to be Human Carcinogens
   b. Reasonably Anticipated to be Human Carcinogens

2. U.S. Environmental Protection Agency (EPA), National Center for Environmental Assessment, Integrated Risk Information System (IRIS) Database

   IRIS, a database created by EPA to assess the risk posed by carcinogenic compounds, contains several chemical lists that have been reviewed for carcinogenic impact over more than 20 years. The following categories are used in QCAT:
   a. 1999 and 2005 Guidelines:
      i. Carcinogenic to humans
      ii. Likely to be carcinogenic to humans
      iii. Suggestive evidence of carcinogenicity
      iv. Not likely to be carcinogenic to humans
   b. 1996 Guidelines:
      i. Known/likely human carcinogen

c. 1986 Guidelines:
    i. Group A: Human carcinogen
    ii. Group B1: Probable human carcinogen
    iii. Group B2: Probable human carcinogen
    iv. Group C: Possible human carcinogen
    v. Group E: Evidence of non-carcinogenicity

3. International Agency for Research on Cancer (IARC), Agents Reviewed by the IARC Monographs.

   IARC reviews chemicals for carcinogenic impact and places them into several categories. The following categories are used within QCAT:
   a. Group 1: Carcinogenic to humans
   b. Group 1: Carcinogenic to humans-inhaled from occupational sources
   c. Group 2A: Probably carcinogenic to humans
   d. Group 2A: Probably carcinogenic to humans-inhaled from occupational sources
   e. Group 2b: Possibly carcinogenic to humans
   f. Group 3: Suggestive evidence of carcinogenicity
   g. Group 4: Probably not carcinogenic to humans

4. State of California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (OEHHA) California Proposition 65 (Safe Drinking Water and Toxic Enforcement Act of 1986) Chemicals Known to the State to Cause Cancer or Reproductive Toxicity.

   OEHHA evaluates chemicals for carcinogenic impact and those likely to demonstrate carcinogenic impact are placed on the Prop 65 list. Presence on the list is indicative of carcinogenicity concerns and is used within QCAT. Note: caution should be taken that placement on the Prop 65 list is for carcinogenicity and not reproductive toxicity concerns.

5. European Commission (EC), Classification and Labeling Inventory (CLP) database, Carcinogens, Mutagens, and Reproductive Toxicants (EU CMR (2)).

   The CLP includes data on chemicals that have been reported for registration under REACH. It also includes information from previous work including data on chemicals evaluated for carcinogenicity, mutagenicity, and reproductive impact. Chemicals found to contain sufficient carcinogenic potential are placed within specific categories. The following categories are used within QCAT:
   a. Carcinogen: Category 1A-known carcinogen
   b. Carcinogen: Category 1B-presumed carcinogen
   c. Carcinogen: Category 2-suspected carcinogen

6. EC, Enterprise and Industry DG – See consolidated version of Annex I of Directive 76/769 EEC, which includes Annex I of Directive 65/548/EEC, which was to be replaced by Annex XVII of REACH on 1 June 2009. (EC CMR (1))

Annex XVII identifies chemicals reviewed and found to contain potential carcinogenic impact. Any chemical found to possess sufficient carcinogenic potential needs to be placed within specific categories. The following categories are used within QCAT:

a. Carcinogen Category 1: Known to be carcinogenic to man
b. Carcinogen Category 2: Regarded as if they are carcinogenic to man
c. Carcinogen Category 3: Possibly carcinogenic to man

7. EC, Regulation on the Classification, Labeling and Packaging of Substances and Mixtures (CLP), EC 1272/2008 and *subsequent amendments*. Originally published in ECB, Annex I of Directive 67-548-EEC and subsequent amendments/adaptations, known as the Dangerous Substances Directive (DSD) or Directive on Dangerous Substances (DDS). EU CMR, Table 3.1 and similar information. Data found in Annex VI, Tables 3-1 & Table 3-2.

   Annex VI identifies chemicals that have been reviewed and found to contain potential carcinogenic impact. Any chemical found to possess sufficient carcinogenic potential is assigned specific risk and/or hazard phrases. The following risk and/or hazard phrases are used within QCAT:

   a. R45: May cause cancer
   b. R49: May cause cancer by inhalation
   c. R40: Limited evidence of carcinogenicity
   d. H350: May cause cancer
   e. H350i: May cause cancer by inhalation
   f. H351: Suspected of causing cancer

8. EC, Risk Substances with EU Risk & Safety Phrases (EU R-Phrases), Commission Directive 67-548-EEC, Annex I.

   Annex I identifies chemicals that have been reviewed and found to contain potential carcinogenic impact. Any chemical found to possess sufficient carcinogenic potential is assigned specific risk phrases. The following risk phrases are used within QCAT:

   a. R45: May cause cancer
   b. R49: May cause cancer by inhalation
   c. R40: Limited evidence of carcinogenicity

9. U.S. Centers for Disease Control, National Institute for Occupational Safety and Health (NIOSH) Carcinogen List.

   NIOSH reviews chemicals for negative potential carcinogenic impacts. If any are found they are placed on a list of carcinogenic compounds, into different categories. The following categories are used within QCAT:

   a. Occupational carcinogen
   b. Identified as potential carcinogen

10. European Commission's REACH list of carcinogens is identified in the Candidate List of Substances of Very High Concern (SVHC) for authorization (listed as EC-REACH SVHCs).

The SHVC list identifies chemicals with sufficient concern to be restricted under REACH. Chemicals placed on the SVHC list due to carcinogenic concerns are used within QCAT to assign a level of concern. Note: Only identify those chemicals placed on the SVHC list for carcinogenicity and not some other hazard concern. Other reasons for SVHC listing will be explained in the relevant hazard criteria.

11. German MAK - List of Substances with MAK and BAT Values and Categories. Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area.

    The German MAK reviews chemicals that impact worker health and safety. Any that are found with identified toxicity concerns are placed into several groups. Chemicals identified by the following groups are used to establish a level of concern within QCAT:
    a. Carcinogen Group 1: Substances that cause cancer in man
    b. Carcinogen Group 2: Considered to be carcinogenic for man
    c. Carcinogen Group 3A: Evidence of carcinogenic effects
    d. Carcinogen Group 3B: Evidence of carcinogenic effects

Human Health: Mutagenicity/Genotoxicity

1. EC, Regulation on the Classification, Labeling and Packaging of Substances and Mixtures (CLP), EC 1272/2008 and subsequent amendments. Originally published in ECB, Annex I of Directive 67-548-EEC and subsequent amendments/adaptations, known as the Dangerous Substances Directive (DSD) or Directive on Dangerous Substances (DDS). EU CMR, Table 3.1 and similar information. Data Found in Annex VI, Tables 3-1 & Table 3-2.

    Annex VI identifies chemicals that have been reviewed and found to contain potential mutagenicity/ genotoxicity impacts. Any chemical found to possess sufficient mutagenicity/genotoxicity potential is assigned specific risk and/or hazard phrases. The following risk and hazard phrases are used within QCAT:
    a. H340: May cause genetic defects
    b. H341: Suspected of causing genetic defects
    c. R46: May cause heritable genetic damage
    d. R68: Strong evidence of heritable genetic damage

2. EC, Enterprise and Industry DG – See consolidated version of Annex I of Directive 76/769 EEC, which includes Annex I of Directive 65/548/EEC, which was replaced by Annex XVII of REACH on 1 June 2009. (EC CMR (1)) Data found in Annex VI, Tables 3-1 & Table 3-2.

    Annex XVII identifies chemicals that were reviewed and found to contain potential mutagenicity/genotoxicity impact. Any chemical found to possess sufficient mutagenicity/genotoxicity potential is placed within specific categories. The following three categories are used within QCAT:
    a. Category 1: Known to be mutagenic to man
    b. Category 2: Regarded as mutagenic to man
    c. Category 3: Suspected to be mutagenic to man

3. European Chemical Agency's (ECHA) list of mutagens identified in the Candidate List of Substances of Very High Concern (SVHC) for authorization.

   The SHVC list identifies chemicals with sufficient concern to be restricted under REACH. Chemicals placed on the SVHC list due to mutagenicity/genotoxicity concerns are used within QCAT to assign a level of concern. Note: Only identify those chemicals placed on the SVHC list for mutagenicity/genotoxicity and not some other hazard concern. Other reasons for listing on the SVHC list will be explained in the relevant hazard criteria.

4. EC, Classification and Labeling Inventory (CLP) database, Carcinogens, Mutagens, and Reproductive Toxicants (EU CMR (2)).

   The CLP includes data on chemicals reported for registration under REACH. It also includes information from previous work including data on chemicals evaluated for carcinogenicity, mutagenicity, and reproductive impact. Chemicals found to contain sufficient carcinogenic potential are placed within specific categories. The following categories are used within QCAT:
   a. Mutagen Category 1A: Known to be mutagenic/genotoxic
   b. Mutagen Category 1B: Presumed to be mutagenic/genotoxic
   c. Mutagen Category 2: Suspected to be mutagenic/genotoxic

5. EC, Risk Substances with EU Risk & Safety Phrases (EU R-Phrases), Commission Directive 67-548-EEC, Annex I.

   The CLP includes data on chemicals reported for registration under REACH. It also includes information from previous work including data on chemicals evaluated for carcinogenicity, mutagenicity, and reproductive impact. Chemicals found to contain sufficient carcinogenic potential are placed within specific categories. The following categories are used within QCAT:
   a. R46: May cause heritable genetic damage
   b. R68: Strong evidence of heritable genetic damage

Human Health: Reproductive toxicity

Note to user: These data sources are often the same as needed for Developmental, so check both at the same time.

1. EC, Regulation on the Classification, Labeling and Packaging of Substances and Mixtures (CLP), EC 1272/2008 and subsequent amendments. Originally published in ECB, Annex I of Directive 67-548-EEC and subsequent amendments/adaptations, known as the Dangerous Substances Directive (DSD) or Directive on Dangerous Substances (DDS). Data found in Annex VI, Tables 3-1 & Table 3-2.

   Annex VI identifies chemicals that have been reviewed and found to contain potential reproductive impact. Any chemical found to possess sufficient reproductive potential is assigned specific risk and/or hazard phrases. The following risk and hazard phrases are used within QCAT:
   a. H360F: May damage fertility.
   b. H360FD: May damage fertility. May damage the unborn child.

c. H360Fd: May damage fertility. Suspected of damaging the unborn child.
d. H360 Df: May damage unborn. Suspected of damaging fertility.
e. H361f: Suspected of damaging fertility.
f. H361fd: Suspected of damaging fertility and unborn child.
g. R60: May impair fertility.
h. R62: Possible risk of impaired fertility.

2. EC, Enterprise and Industry DG - See consolidated version of Annex I of Directive 76/769 EEC, which includes Annex I of Directive 65/548/EEC, which was replaced by Annex XVII of REACH on 1 June 2009. (EC CMR (1))

   Annex XVII identifies chemicals that have been reviewed and found to contain potential reproductive toxicity impact. Any chemical found to possess sufficient reproductive toxicity potential is placed within specific categories. The following categories are used within QCAT:
   a. Category 1: Known or presumed human reproductive or developmental toxicant
   b. Category 2: Presumed reproductive toxicant

3. EC, Risk Substances with EU Risk & Safety Phrases (EU R-Phrases), Commission Directive 67-548-EEC, Annex I.

   Annex I identifies chemicals that have been reviewed and found to contain potential reproductive toxicity impact. Any chemical found to possess sufficient reproductive toxicity potential is assigned specific risk phrases. The following risk phrases are used within QCAT:
   a. R60: May impair fertility
   b. R62: Possible risk of impaired fertility

4. EC, Classification and Labeling Inventory (CLP) database, Carcinogens, Mutagens and Reproductive Toxicants (EU CMR (2)).

   The CLP lists chemicals that have been evaluated for reproductive toxicity as well as carcinogenicity and reproductive impact. Chemicals found to contain sufficient reproductive toxicity potential are placed within specific categories. The following categories are used within QCAT:
   a. Reproductive Tox. Category 1A: Known reproductive toxicant
   b. Reproductive Tox: Category 1B: Presumed reproductive toxicant
   c. Reproductive Tox. Category 2: Suspected reproductive or developmental toxicant

5. State of California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (OEHHA) California Proposition 65 (Safe Drinking Water and Toxic Enforcement Act of 1986), Chemicals Known to the State to Cause Cancer or Reproductive Toxicity.

   OEHHA evaluates chemicals for reproductive toxicity impact and those likely to demonstrate reproductive toxicity impact are placed on the Prop 65 list. Presence on the list is indicative of reproductive toxicity concerns and is used within QCAT. Note: caution should be taken that the reason for placement on the Prop 65 list is reproductive toxicity and not carcinogenicity.

6. U.S. National Institutes of Health, National Institute of Environmental Health Sciences, National Toxicology Program (NTP), Health Assessment and Translation (Formerly CERHR). NTP-OHAT Monographs on the Potential Human Reproductive and Developmental Effects.

   NTP creates lists of chemicals that have been reviewed for reproductive toxicity impacts. The following categories are used to assess level of concern in QCAT.
   a. Cat. A: Clear evidence of adverse reproductive toxicant effects.
   b. Cat. B: Limited or some evidence of Adverse Effects-Reproductive toxicity

7. European Commission's REACH list of chemicals 'toxic for reproduction' identified in the Candidate List of Substances of Very High Concern (SVHC) for authorization. (listed as EC-REACH SVHCs)

   The SHVC list identifies chemicals with sufficient concern to be restricted under REACH. Chemicals placed on the SVHC list due to reproductive toxicity concerns are used within QCAT to assign a level of concern. Note: Only identify those chemicals placed on the SVHC list for reproductive toxicity and not some other hazard concern. Other reasons for SVHC listing will be explained in the relevant hazard criteria.

Human Health: Development (including developmental neurotoxicity)

1. EC, Regulation on the Classification, Labeling and Packaging of Substances and Mixtures (CLP), EC 1272/2008 and subsequent amendments. Originally published in ECB, Annex I of Directive 67-548-EEC and subsequent amendments/adaptations, known as the Dangerous Substances Directive (DSD) or Directive on Dangerous Substances (DDS). Data found in Annex VI, Tables 3-1 & Table 3-2. Annex VI identifies chemicals that have been reviewed and found to contain potential developmental impact. Any chemical found to possess sufficient developmental potential is assigned specific hazard phrases. The following hazard phrases are used within QCAT:
   a. H360D: May damage the unborn child
   b. H360FD: May damage fertility or the unborn child
   c. H360Df: May damage the unborn child. Suspected of damaging fertility.
   d. H362: May cause harm to breast-fed children.
   e. H360Fd-Suspected of impacting fertility or unborn child
   f. H361d-Suspected of damaging fertility or unborn child
   g. H361fd-Suspected of damaging fertility & unborn child

2. EC, Risk Substances with EU Risk & Safety Phrases (EU R-Phrases), Commission Directive 67-548-EEC, Annex I.

   Annex I identifies chemicals that have been reviewed and found to contain potential developmental impact. Any chemical found to possess sufficient developmental potential is assigned specific risk phrases. The following risk phrases are used within QCAT:
   a. R61: May cause harm to the unborn child
   b. R64: May cause harm to breast-fed babies
   c. R63: Possible risk of harm to unborn child

3. State of California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (OEHHA) California Proposition 65 (Safe Drinking Water and Toxic Enforcement Act of 1986), Chemicals Known to the State to Cause Cancer or Reproductive Toxicity.

   OEHHA evaluates chemicals for reproductive toxicity/developmental impact and any that are likely to demonstrate reproductive/developmental impact are placed on the Prop 65 list. Presence on the list is indicative of reproductive/developmental toxicity concerns and is used within QCAT. Note: caution should be taken that the reason for placement on the Prop 65 list is reproductive toxicity and not carcinogenicity.

4. U.S. National Institutes of Health, National Institute of Environmental Health Sciences, National Toxicology Program (NTP), Health Assessment and Translation (Formerly CERHR). NTP-OHAT Monographs on the Potential Human Reproductive and Developmental Effects.

   NTP creates lists of chemicals that have been reviewed for developmental toxicity. Chemicals assigned the following categories are used in QCAT to assign level of concern.
   a. Category A: Clear evidence of adverse developmental toxicant effects.
   b. Category B: Some evidence of adverse developmental toxicant effects.
   c. Category C: Limited evidence of Adverse Effects-Dev.
   d. Category E: Limited or some of No Adverse Effects-Dev.
   e. Category F: Some evidence of no adverse Effects-Dev.
   f. Category G: Clear evidence of No Adverse Effects- Dev.

Human Health: Endocrine Activity

1. European Commission's REACH list of chemicals 'other serious concerns specifically for endocrine activity' identified in the Candidate List of Substances of Very High Concern (SVHC) for authorization. (listed as EC-REACH SVHCs)

   The SHVC list identifies chemicals with sufficient concern to be restricted under REACH. Chemicals placed on the SVHC list due to endocrine activity concerns are used within QCAT to assign a level of concern. Note: Only identify those chemicals placed on the SVHC list for endocrine activity and not some other hazard concern. Other reasons for SVHC listing will be explained in the relevant hazard criteria.

Human Health: Acute Mammalian Toxicity

There are few general acute mammalian toxic compounds identified in Step I sources. This is because category duplicates the chemicals found in the specific categories of carcinogenicity, reproductive toxicity, PBT, etc. Additional sources are available in Step II that evaluates toxicity from a broader perspective.

1. EC, Regulation on the Classification, Labeling and Packaging of Substances and Mixtures (CLP), EC 1272/2008 and subsequent amendments. Originally published in ECB, Annex I of Directive 67-548-EEC and subsequent amendments/adaptations, known as the Dangerous Substances Directive (DSD)

or Directive on Dangerous Substances (DDS). EU CMR, Table 3.1 and similar information. Data found in Annex VI, Tables 3-1 & Table 3-2.

Annex VI identifies chemicals that have been reviewed and found to contain potential carcinogenic impact. Any chemical found to possess sufficient carcinogenic potential is assigned specific hazard and/or risk phrases. The following hazard and risk phrases are used within QCAT:

a. R26: Very toxic via inhalation
b. R27: Very toxic via skin
c. R28: Very toxic if swallowed
d. R23: Toxic via inhalation
e. R24: Toxic via skin
f. R25: Toxic if swallowed
g. R20: Harmful via inhalation
h. R21: Harmful via skin
i. R22: Harmful if swallowed
a. H301: Toxic if swallowed
b. H311: Toxic in contact with skin
c. H331: Toxic if inhaled

2. EC, Risk Substances with EU Risk & Safety Phrases (EU R-Phrases), Commission Directive 67-548-EEC, Annex I.

Annex I identifies chemicals that have been reviewed and found to contain potential acute mammalian impact. Any chemical found to possess sufficient carcinogenic potential is assigned specific risk phrases. The following risk phrases are used in QCAT:

a. R26: Very toxic via inhalation
b. R27: Very toxic via skin
c. R28: Very toxic if swallowed
d. R23: Toxic via inhalation
e. R24: Toxic via skin
f. R25: Toxic if swallowed
g. R20: Harmful via inhalation
h. R21: Harmful via skin
i. R22: Harmful if swallowed

Environmental Health: Acute Aquatic Toxicity

1. European Commission's REACH list of chemicals 'PBTs because of ecotoxicity' identified in the Candidate List of Substances of Very High Concern (SVHC) for authorization. (listed as EC – REACH SVHCs)

The SHVC list identifies chemicals with sufficient concern to be restricted under REACH. Chemicals placed on the SVHC list due to acute aquatic toxicity concerns are used within QCAT to assign a level of concern. Note: Only identify those chemicals placed on the SVHC list for acute aquatic toxicity and not some other hazard concern. Other reasons for SVHC listing will be explained in the relevant hazard criteria.

2. EC, Risk Substances with EU Risk & Safety Phrases (EU R-Phrases), Commission Directive 67-548-EEC, Annex I.

Annex I identifies chemicals that have been reviewed and found to contain potential acute aquatic toxicity impacts. Any chemical found to possess sufficient acute aquatic toxicity potential is assigned specific risk phrases. The following risk phrases are used within QCAT:

a. R50: Very toxic to aquatic life
b. R51: Toxic to aquatic life

c. R52: Harmful to aquatic life

There are currently very few additional authoritative lists available for acute aquatic toxicity. As additional authoritative lists of chemicals with acute aquatic toxicity become available, they will be added to the QCAT. Until that point, there are other Step II data sources available, which will allow identification of acute aquatic toxicity for the QCAT.

Environmental Fate: Persistent, Bioaccumulative and Toxic (PBT) Substances[13]

1. United Nations Environment Programme (UNEP), Stockholm Convention Secretariat Stockholm Convention on Persistent Organic Pollutants (POPs).

   The UNEP identifies lists of persistent chemicals of concern. Presence on any of these lists is indicative of meeting the persistence criteria and is used to identify a level of concern within QCAT.

The four sources of information include:

a. List of 12 POPs under the convention.
b. List of nine new POPs.
c. List of chemicals in review process.
d. May degrade to PFOS.

2. U.S. Environmental Protection Agency (EPA), Toxics Release Inventory (TRI) Program, TRI PBT Chemical List.

   EPA's TRI Program has identified chemicals, which meet EPA's persistence criteria. Presence on this list is used with QCAT to assign a level of concern.

3. EPA, Persistent Bioaccumulative and Toxic (PBT) Chemical Program, Priority PBT Profiles.

   EPA's PBT Program has identified chemicals, which meet EPA's persistence criteria. Presence on this list is used with QCAT to assign a level of concern.

4. EPA, National Waste Minimization Program Priority (NWMP Priority) Chemicals List.

   EPA's NWMP Program has identified chemicals, which meet EPA's persistence criteria. Presence on this list is used with QCAT to assign a level of concern.

5. European Commission/Oslo-Paris Convention (OSPAR), Chemicals of Possible Concern. (listed as EC/Oslo-Paris Conv.)

   OSPAR has identified chemicals, which potentially meet their persistence criteria. Presence on this list is used with QCAT to assign a level of concern.

[13] Note: These are lists of chemicals that meet **both** the persistent and bioaccumulative requirements. If a chemical appears on these lists, they are high for both bioaccumulation and persistence hazard endpoints.

6. European Commission/Oslo-Paris Convention (OSPAR), Chemicals for Priority Action. (listed as EC/Oslo-Paris Conv.)

   OSPAR has identified priority chemicals, which meet their persistence criteria. Presence on this list is used with QCAT to assign a level of concern.

7. European Commission's REACH list of PBTs identified in the Candidate List of Substances of Very High Concern (SVHC) for authorization. (listed as EC – REACH SVHCs)

   The SHVC list identifies chemicals with sufficient concern to be restricted under REACH. Chemicals placed on the SVHC list due to persistence concerns are used within QCAT to assign a level of concern. Note: Only identify those chemicals placed on the SVHC list for persistence (typically PBT) and not some other hazard concern. Other reasons for SVHC listing will be explained in the relevant hazard criteria.

Environmental Fate: very Persistent and very Bioaccumulative (vPvB) Substances[14]

1. European Commission's REACH list of very persistent, very bioaccumulative (vPvB) chemicals identified in the Candidate List of Substances of Very High Concern (SVHC) for authorization. (listed as EC – REACH SVHCs)

   The SHVC list identifies chemicals with sufficient concern to be restricted under REACH. Chemicals placed on the SVHC list due to persistence concerns are used within QCAT to assign a level of concern. Note: Only identify those chemicals placed on the SVHC list for persistence (vPvB) and not some other hazard concern. Other reasons for SVHC listing will be explained in the relevant hazard criteria.

Appendix 2: Step II Data Sources

For the purposes of the QCAT, the following databases and information sources will be searched for specific information, which can be used to grade chemicals undergoing the assessment process. Although considerable information is available from all of these sources, only specific information will be selected for review in support of the objectives of the QCAT to limit the level of technical expertise necessary. Information used from each database will be described in detail at the end of this appendix.

For endocrine disruptors, available government lists are preliminary screening lists that identify prime candidates for the high concern label; however, these chemicals need further assessment before being identified as endocrine disruptors with certainty. The same can be said for neurotoxicants. Grandjean and Landrigan (2008) identified 201 potential developmental toxicants. These chemicals also require further research to determine if they pose a developmental threat. Since neurotoxicity and endocrine activity are endpoints of high concern, these "watch" lists are provided as they flag chemicals that may meet these criteria. While these chemicals are under assessment, avoidance is warranted.

[14] Note: These are lists of chemicals that meet **both** the persistent and bioaccumulative requirements. If a chemical appears on these lists, it is very high for both bioaccumulation and persistence hazard endpoints.

Databases to be found in Step II of the QCAT include:

1. European Chemicals Agency, Classification and Labeling Database (C&L Database).
2. KEMI, Swedish Chemical Agency's N-Class Database providing risk phrase information on environmental hazard classification.
3. National Library of Medicine (NLM), Hazardous Substances Databank (HSDB).
4. National Institute of Occupational Safety and Health (NIOSH), Registry of Toxic Effects of Chemical Substances (RTECS).
5. U.S. Department of Labor, Occupational Safety & Health Administration (OSHA) Occupational Chemical Database.
6. ISSCAN: InstitutoSuperiore di Sanita, 'Chemical Carcinogens: Structures and Experimental Data.' Additional information may also be available.
7. The United Nation's Screening Information Datasets (SIDS), if available.
8. Grandjean, P & PJ Landrigan, 2006, *Developmental neurotoxicity of industrial chemicals*, **The Lancet**, v.368: 2167-2178.

Information on how to access information within the database will be presented later in this appendix after the list of data sources for each individual hazard endpoint.

Human Health: Carcinogenicity

1. The International Uniform Chemical Information Database (IUCLID) dataset, if available.

   IUCLID datasets may be referenced in other sources. However, the assessor may download a copy of IUCLID 5.6 and determine whether a dataset is available. If a IUCLID data sheet is available, the document can be evaluated for evidence of carcinogenicity above and beyond the Step I sources. More information on how to determine if these documents contain additional information can be found in the subsequent screen-capture section.

2. National Library of Medicine (NLM), Hazardous Substances Database (HSDB).

   HSDB may contain information found in Step I sources. However, it may also report data beyond Step I sources. The assessor should select the 'full record' option and then search on portions of the term 'carcinogenicity.' More information on how to search the HSDB for this additional data is in the following screen-capture section.

3. National Institute of Occupational Safety and Health (NIOSH), Registry of Toxic Effects of Chemical Substances (RTECS).

   RTECS is a toxicological database that contains peer-reviewed information from international journals, textbooks, technical reports, scientific proceedings, etc. RTECS reports the results of this

review. For carcinogenicity, RTECS will not provide specific numerical values for evaluation but evidence on whether or not the chemical of concern demonstrates carcinogenic characteristics.

The assessor should determine from this review whether RTECS provides evidence of carcinogenicity and to what degree, i.e., strong, moderate, or low. More information is provided in the following screen-capture section.

4. U.S. Department of Labor, Occupational Safety & Health Administration (OSHA) Occupational Chemical Database.

   OSHA maintains chemical information relevant to protecting workers and the public in case of an accidental release. This information can be reviewed to determine if the chemical presents any carcinogenic concern. Specifically, the database contains a section labeled 'Carcinogen Classifications,' which identifies any carcinogenic concerns associated with the chemical.

5. Japanese Government National Institute of Technology and Evaluation (NITE) for estimated Risk Phrases, if available.

   NITE evaluates existing information and determines a level of concern for each chemical. The following levels of concern are used within QCAT:
   a. Carcinogenic: Category 1
   b. Carcinogenic: Category 1A
   c. Carcinogenic: Category 1B

6. Korea National Institute of Environmental Research (NIER), GHS Classification and Labeling for Toxic Chemicals.

   NIER evaluates data for specific chemicals and identifies an equivalent hazard phrase. This hazard phrase is used within QCAT:
   a. H350: May cause cancer

7. New Zealand Environmental Protection Authority, Hazardous Substance and New Organisms (HSNO) Chemical Classifications (GHS-New Zealand).

   HSNO evaluates chemicals and ranks them for level of concern. One level of concern appropriate for carcinogenicity is:
   a. 6.7 A: Known or presumed human carcinogens
   b. 6.7 B: Suspected human carcinogens

8. ISSCAN: InstitutoSuperiore di Sanita, 'Chemical Carcinogens: Structures and Experimental Data.' Additional information may also be available.

   ISSCAN evaluates chemicals and ranks them for level of concern. These rankings can translate into an equivalent level of concern within QCAT:
   a. Ranking = 3: Carcinogenic

b. Ranking = 2: Undetermined or equivocal
c. Ranking = 1: Non-carcinogenetic

9. The United Nation's Screening Information Datasets (SIDS), if available.

   SIDS reports the results of studies and other information relevant to carcinogenicity. Typically, the results are summarized and this information can be reviewed to determine whether evidence of carcinogenicity exists for the chemical of concern. The assessor reviews this information to determine the level of concern. More information is available in the following screen-capture section.

Human Health: Mutagenicity/Genotoxicity

1. The International Uniform Chemical Information Database (IUCLID) dataset, if available.

   IUCLID datasets may be referenced in other sources. However, the assessor may download a copy of IUCLID 5.6 and determine whether a dataset is available. If a IUCLID data sheet is available, the document can be evaluated for evidence of carcinogenicity above and beyond the Step I sources. More information on how to determine if these documents contain additional information can be found in the subsequent screen-capture section.

2. National Library of Medicine (NLM), Hazardous Substances Database (HSDB).

   HSDB may contain information found in Step I sources. However, it may also report data beyond Step I sources. The assessor should select the 'full record' option and search on portions of the term 'carcinogenicity.' More information on how to search the HSDB for this additional data can be found in the following screen-capture section.

3. Japanese Government National Institute of Technology and Evaluation (NITE) for estimated Risk Phrases, if available.

   NITE evaluates existing information and determines a level of concern for each chemical. These levels of concern are used within QCAT:
   a. Germ cell mutagenicity: Category 1B

4. Korea National Institute of Environmental Research (NIER), GHS Classification and Labeling for Toxic Chemicals.

   NIER evaluates data for specific chemicals and identifies an equivalent hazard phrase. This hazard phrase is used within QCAT:
   a. H340: May cause genetic effects

5. New Zealand Environmental Protection Authority, Hazardous Substance and New Organisms (HSNO) Chemical Classifications (GHS-New Zealand).

   HSNO evaluates chemicals and ranks them for level of concern. One level of concern appropriate for carcinogenicity is:

a. 6.6 A: Known or presumed human mutagens

6. National Institute of Occupational Safety and Health (NIOSH), Registry of Toxic Effects of Chemical Substances (RTECS).

   RTECS is a toxicological database that contains peer-reviewed information from international journals, textbooks, technical reports, scientific proceedings, etc. RTECS reports the results of this review. For mutagenicity/genotoxicity, RTECS will not provide specific numerical values for evaluation but evidence on whether or not the chemical of concern demonstrates mutagenic/genotoxic characteristics. The assessor should determine from this review whether RTECS provides evidence of mutagenicity/genotoxicity and to what degree, i.e., strong, moderate, or low. More information is provided in the following screen-capture section.

7. The United Nation's Screening Information Datasets (SIDS), if available.

   SIDS reports the results of studies and other information relevant to mutagenicity/genotoxicity. Typically the results are summarized and this information can be reviewed to determine whether evidence of mutagenicity/genotoxicity exists for the chemical of concern. The assessor reviews this information to determine the level of concern. More information is available in the following screen-capture section.

8. German MAK - List of Substances with MAK and BAT Values and Categories. Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area.

   The German MAK reviews chemicals that impact worker health and safety. Any that are found with identified toxicity concerns are placed into several groups. Chemicals identified can be used to establish a level of concern within QCAT.
   a. Germ cell mutagen 1
   b. Germ cell mutagen 2

Human Health: Reproductive Toxicity

Note to user: These data sources are often the same as needed for Developmental, so check for both at the same time.

1. The International Uniform Chemical Information Database (IUCLID) dataset, if available

   IUCLID datasets may be referenced in other sources. However, the assessor may download a copy of IUCLID 5.6 and determine whether a dataset is available. If a IUCLID data sheet is available, the document can be evaluated for evidence of carcinogenicity above and beyond the Step I sources. More information on how to determine if these documents contain additional information can be found in the subsequent screen-capture section.

2. Japanese Government National Institute of Technology and Evaluation (NITE) for estimated Risk Phrases, if available.

NITE evaluates existing information and determine a level of concern for each chemical. The following levels of concern are used within QCAT:

a. Toxic to reproduction: Category 1
b. Toxic to reproduction: Category 1A
c. Toxic to reproduction: Category 1B

3. Korea National Institute of Environmental Research (NIER), GHS Classification and Labeling for Toxic Chemicals.

   NIER evaluates data for specific chemicals and identifies an equivalent hazard phrase. This hazard phrase is used within QCAT:

   a. H360: May damage fertility or the unborn child

4. New Zealand Environmental Protection Authority, Hazardous Substance and New Organisms (HSNO) Chemical Classifications (GHS-New Zealand).

   HSNO evaluates chemicals and ranks them for level of concern. One level of concern appropriate for reproductive toxicity is:

   a. 6.8 A: Known or presumed human reproductive or developmental toxicants

5. National Library of Medicine (NLM), Hazardous Substances Database (HSDB).

   HSDB may contain information found in Step I sources. However, it may also report data beyond Step I sources. The assessor should select the 'full record' option and search on portions of the term 'reproductive.' More information on how to search the HSDB for this additional data is in the following screen-capture section.

6. The United Nation's Screening Information Datasets (SIDS), if available.

   SIDS reports the results of studies and other information relevant to reproductive toxicity. Typically the results are summarized and this information can be reviewed to determine whether evidence of reproductive toxicity exists for the chemical of concern. The assessor also reviews this information to determine the level of concern. More information is available in the following screen-capture section.

Human Health: Developmental Toxicity (including Developmental Neurotoxicity)

1. The International Uniform Chemical Information Database (IUCLID) dataset, if available

   IUCLID datasets may be referenced in other sources. However, the assessor may download a copy of IUCLID 5.6 and determine whether a dataset is available. If a IUCLID data sheet is available, the document can be evaluated for evidence of carcinogenicity above and beyond the Step I sources. More information on how to determine if these documents contain additional information can be found in the subsequent screen-capture section.

2. Grandjean, P & PJ Landrigan, 2006, *Developmental neurotoxicity of industrial chemicals*, **The Lancet**, v.368: 2167-2178.

   This is a list of 201 chemicals with evidence suggesting developmental neurotoxicity in humans. Presence on the list is indicative of concern and is used in QCAT for determining a level of concern.

3. National Library of Medicine (NLM), Hazardous Substances Database (HSDB).

   HSDB may contain information found in Step I sources. However, it may also report data beyond Step I sources. The assessor should select the 'full record' option and search on portions of the term 'developmental.' More information on how to search the HSDB for this additional data can be found in the following screen-capture section.

4. The United Nation's Screening Information Datasets (SIDS), if available.

   SIDS reports the results of studies and other information relevant to developmental toxicity. Typically, the results are summarized and this information can be reviewed to determine whether or not evidence of developmental toxicity exists for the chemical of concern. The assessor reviews this information to determine the level of concern. More information is available in the following screen-capture section.

5. German MAK - List of Substances with MAK and BAT Values and Categories. Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area.

   The German MAK reviews chemicals that impact worker health and safety. Any that are found with identified toxicity concerns are placed into several groups. Those chemicals identified by the following groups are used to establish a level of concern for developmental toxicity within QCAT:
   a. Pregnancy Risk Group A
   b. Pregnancy Risk Group B

Human Health: Endocrine Activity

1. The International Uniform Chemical Information Database (IUCLID) dataset, if available.

   IUCLID datasets may be referenced in other sources. However, the assessor may download a copy of IUCLID 5.6 and determine whether a dataset is available. If a IUCLID data sheet is available, the document can be evaluated for evidence of carcinogenicity above and beyond the Step I sources. More information on how to determine if these documents contain additional information can be found in the subsequent screen-capture section

2. National Institute of Occupational Safety and Health (NIOSH), Registry of Toxic Effects of Chemical Substances (RTECS).

   RTECS is a toxicological database that contains peer-reviewed information from international journals, textbooks, technical reports, scientific proceedings, etc. RTECS reports the results of this review. For endocrine activity, RTECS will not provide specific numerical values for evaluation but evidence on whether or not the chemical of concern demonstrates endocrine activity characteristics.

The assessor should determine from this review whether RTECS provides evidence of endocrine activity and to what degree, i.e., strong, moderate, or low. More information will be provided in the following screen-capture section.

3. European Commission/Oslo-Paris Convention (OSPAR), Chemicals of possible concern identified as potential endocrine disruptors. (listed as EC/Oslo-Paris Conv)

   OSPAR has identified chemicals with potential endocrine disruptors. This list is very brief and may best be determined by reviewing the Excel spreadsheet summarizing the data for each chemical. QCAT uses presence on this list to assign a level of concern.

4. European Commission, Endocrine Disruptor Database. Endocrine Disruptors Screening List.

   In 2007, the EC released a database containing 575 chemical substances screened for endocrine disrupting effects. Chemicals were separated into several categories:
   a. Category 1: Known to impair fertility or cause developmental toxicity
   b. Category 2: Impairs fertility or causes developmental toxicity
   c. Category 3b: Some evidence of endocrine activity

5. The Endocrine Disruption Exchange (TEDX) Potential Endocrine Disruptors.

   TEDX is an organization that focuses primarily on the human health and environmental problems caused by low-dose and/or ambient exposure to chemicals that interfere with development and function, called endocrine disruptors. Presence on the list of potential endocrine active compounds is used by QCAT to assign a level of concern.

6. EC, EU Community Strategy for Endocrine Disrupters Priority Endocrine Disrupters (EU ED) list.

   The EU established a list of chemicals to be evaluated for endocrine activity based upon research indicating potential endocrine impact and places the chemical into various categories depending on the evidence available. The categories are used with QCAT to identify a level of concern.
   a. Category 1: In vivo evidence of endocrine disruption activity
   b. Category 2: In vitro evidence of biological activity related to endocrine activity

Human Health: Acute Mammalian Toxicity

1. The International Uniform Chemical Information Database (IUCLID) dataset, if available.

   IUCLID datasets may be referenced in other sources. However, the assessor may download a copy of IUCLID 5.6 and determine whether a dataset is available. If a IUCLID data sheet is available, the document can be evaluated for evidence of carcinogenicity above and beyond the Step I sources. More information on how to determine if these documents contain additional information can be found in the subsequent screen-capture section.

2. National Library of Medicine (NLM), Hazardous Substances Database (HSDB).

   HSDB may report data beyond Step I sources. In the Table of Contents listing in the HSDB, pages can often be found titled 'Non-Human Toxicity Values.' This section may contain data, such as LD_{50} (the lethal dose that kills 50% of the population) for a number of test animal species. This data can be used to determine the level of concern within QCAT by comparing these data results with the Technical Criteria provided within Appendix 8. Information on how to search the HSDB for this additional data is available in the following screen-capture section.

3. National Institute of Occupational Safety and Health (NIOSH), Registry of Toxic Effects of Chemical Substances (RTECS).

   RTECS is a toxicological database that contains peer-reviewed information from international journals, textbooks, technical reports, scientific proceedings, etc. RTECS reports the results of this review. For acute mammalian toxicity, RTECS provide specific numerical values for evaluation such as LD_{50} for a number of test species. This data can be compared against the Technical Criteria in Appendix 8 and used in QCAT to assign a level of concern. More information will be provided in the following screen-capture section.

4. The United Nation Environmental Programme's (UNEP) Screening Information Datasets (SIDS), if available.

   UNEP collects hazard information on a number of chemicals of concern and publishes the information collected and reviewed in SIDS. SIDS separates the hazard information into specific sections and the section on Mammalian Toxicity may contain information such as LD_{50} values that can be compared against the Technical Criteria in Appendix 8 and used in QCAT to assign a level of concern. More information will be provided in the following screen-capture section.
5. Danish Ministry of the Environment's Environmental Protection Agency (Danish EPA) (Q)SAR Assessment of chemical properties of substances database.

   The Danish EPA conducted an analysis of a wide range of chemicals by evaluating potential hazard concerns using computer modeling, which compares the structure of unknown chemicals with specific properties known to cause problems. In this method, if two chemicals contain similar structural components and the component is known to be toxic in one chemical, it is assumed the unevaluated chemical will have the same negative impact. This process is called Qualitative Structure Activity

Relationships or (Q)SARs. (Q)SAR computer modeling is becoming more widely accepted particularly in countries that have concerns about animal testing. The Danish EPA has converted its (Q)SAR results into an Advisory List for Self-classification using the EU's Classification and Labeling Programme's (CLP) risk phrases. These risk phrases can be used in QCAT to assign a level of concern.[15]

6. U.S. EPA, 2001, Consolidated list of chemicals subject to the Emergency Planning and Community Right-To-Know Act (EPCRA) and Section 112(4) of the Clean Air Act (CAA). NOTE: This refers only to the list of chemicals from EPCRA Section 302.

   EPCRA Section 302 contains a list of chemicals with known hazard concerns. Within EPCRA and the CAA, reporting requirements are placed on these chemicals. For the purposes of QCAT, the presence of a chemical on this list is used to assign a level of concern.

Environmental Health: Acute Aquatic Toxicity

1. The International Uniform Chemical Information Database (IUCLID) dataset, if available.

   IUCLID datasets may be referenced in other sources. However, the assessor may download a copy of IUCLID 5.6 and determine whether a dataset is available. If a IUCLID data sheet is available, the document can be evaluated for evidence of carcinogenicity above and beyond the Step I sources. More information on how to determine if these documents contain additional information can be found in the subsequent screen-capture section.

2. KEMI, Swedish Chemical Agency's N-Class Database summarizes information on chemicals of concern.

   This database provides risk phrase information on environmental hazard classification. It includes information found in other sources listed in this document such as the EC Annex I classification results but can also provide information from additional sources. By searching on CAS number, results are reported as 'Aquatic Classification'. This information can be used by QCAT to assign a level of concern.

3. National Library of Medicine (NLM), Hazardous Substances Database (HSDB). HSDB may report data beyond Step I sources.

   In the Table of Contents listing in the HSDB, a page can often be found titled 'Ecotoxicity Values'. This section may contain data such as LC_{50} (the lethal concentration that kills 50% of the population) along with similar results for a number of test animal species. This data can be used to determine the level of concern within QCAT by comparing these data results with the Technical Criteria provided in Appendix 8. Information on how to search the HSDB for this additional data is available in the following screen-capture section.

[15] Note: Care should be taken to find the English version of this website in case the link breaks. It is available both in English and Danish.

4. The United Nation Environmental Programme's (UNEP) Screening Information Datasets (SIDS), if available.

   UNEP collects hazard information on a number of chemicals of concern and publishes the information collected and reviewed in SIDS. SIDS separates the hazard information into specific sections and the section on Aquatic Toxicity may contain information such as LC_{50} values that can be compared against the Technical Criteria in Appendix 8 and used in QCAT to assign a level of concern. More information will be provided in the following screen-capture section.

5. European Commission, Regulation on the Classification, Labeling and Packaging of Substances and Mixtures (CLP), EC 1272/2008 and subsequent amendments. Originally published in ECB, Annex I of Directive 67-548-EEC and subsequent amendments/adaptations, known as the Dangerous Substances Directive (DSD) or Directive on Dangerous Substances (DDS). EU CMR, Table 3.1 and similar information. Data Found in Annex VI, Tables 3-1 & Table 3-2.

   Annex VI identifies chemicals that have been reviewed and found to contain potential carcinogenic impact. Any chemical found to possess sufficient carcinogenic potential is assigned specific risk phrases. The risk phrases are used within QCAT to assign a level of concern.

6. U.S. Environmental Protection Agency (EPA), Ecological Toxicity (ECOTOX) database.

   EPA has collected data on aquatic toxicity and published the results in ECOTOX. Unlike the HSDB and other similar databases, EPA does not do a technical review of the studies but solely publishes the results. For this reason, should other sources that have been reviewed conflict with ECOTOX results, the reviewed studies should be given preference. In the absence of data, ECOTOX provides an excellent resource on the latest aquatic toxicity studies. ECOTOX results are typically reported in values such as $LC_{50,}$ which can be compared against the Technical Criteria in Appendix 8 identifying a level of concern to be used in QCAT. More information is provided in the following screen capture section on how to access data in ECOTOX.

7. New Zealand Environmental Protection Authority, Hazardous Substance and New Organisms (HSNO) Chemical Classifications (GHS-New Zealand).

   HSNO evaluates chemicals and ranks them for level of concern. Levels of concern appropriate for aquatic toxicity include:
   a. A (algal): Very ecotoxic in the aquatic environment
   b. A (crustacean): Very ecotoxic in the aquatic environment
   c. 9.1 A (fish): Very ecotoxic in the aquatic environment
   d. 9.1 A (other): Very ecotoxic in the aquatic environment

Environmental Fate: Persistence & Bioaccumulation

1. State of Washington, Department of Ecology (Ecology), Chapter 173-333 WAC Persistent Bioaccumulative Toxics.

Ecology published a list of chemicals that meet the PBT criteria established in the rule. Presence on this list is used in QCAT to determine a level of concern.

2. Oregon Department of Environmental Quality (Oregon DEQ), Water Quality Division, Priority Persistent Pollutants (OR P3).

   Oregon DEQ established a list of PBT chemicals impacting the state's waters that have a documented effect on human health, wildlife and aquatic life. Presence on the list is used in QCAT to determine a level of concern.

Environmental Fate: Persistence

1. U.S. Environmental Protection Agency (EPA), PBT Profiler.

   The PBT Profiler is a computer model created by EPA as a screening tool to predict a chemical's potential to persist in the environment. Results are reported in half-lives for various media such as water, air, soil, and sediment. These half-lives are compared against the Technical Criteria in Appendix 8 to determine a level of concern in QCAT.

2. The International Uniform Chemical Information Database (IUCLID) dataset, if available.

   IUCLID datasets may be referenced in other sources. However, the assessor may download a copy of IUCLID 5.6 and determine whether a dataset is available. If a IUCLID data sheet is available, the document can be evaluated for evidence of carcinogenicity above and beyond the Step I sources. More information on how to determine if these documents contain additional information can be found in the subsequent screen-capture section.

3. The United Nation's Screening Information Datasets (SIDS), if available.

   UNEP collects hazard information on a number of chemicals of concern and publishes the information collected and reviewed in SIDS. SIDS separates the hazard information into specific sections and the section on Environmental Fate may contain information such as half-life values that can be compared against the Technical Criteria in Appendix 8 and used in QCAT to assign a level of concern. More information will be provided in the following screen-capture section.

4. Canadian Environmental Protection Agency (CEPA) Domestic Substances List (DSL), Bioaccumulative and inherently Toxic chemical (PiT).

   CEPA evaluated chemicals produced or imported into Canada, the DSL, for hazard concerns and published their results in both a database and in Excel spreadsheets for specific criteria. One spreadsheet lists the chemicals that are persistent and inherently toxic to human health and the environment, abbreviated PiT. Presence on this list is used by QCAT to assign a level of concern.

Environmental Fate: Bioaccumulation

1. U.S. Environmental Protection Agency, PBT Profiler.

The PBT Profiler is a computer model created by EPA as a screening tool to predict a chemical's potential to bioaccumulate in the environment. Results are reported in Bioconcentration Factors (BCF). BCF values from the PBT Profiler are compared against the Technical Criteria in Appendix 8 to determine a level of concern in QCAT.

2. The International Uniform Chemical Information Database (IUCLID) dataset, if available.

   IUCLID datasets may be referenced in other sources. However, the assessor may download a copy of IUCLID 5.6 and determine whether a dataset is available. If a IUCLID data sheet is available, the document can be evaluated for evidence of carcinogenicity above and beyond the Step I sources. More information on how to determine if these documents contain additional information can be found in the subsequent screen-capture section.

3. U.S. Environmental Protection Agency, Ecological Toxicity (ECOTOX) database.

   EPA has collected data on aquatic toxicity and published the results in ECOTOX. Unlike the HSDB and other similar databases, EPA does not conduct a technical review of the studies but solely publishes the results. For this reason, should other sources that have been reviewed conflict with ECOTOX results, the reviewed studies should be given preference. In the absence of data, ECOTOX provides an excellent resource on the latest aquatic toxicity studies. ECTOX results can include BCF or BAF values, which can be compared against the Technical Criteria in Appendix 8 identifying a level of concern to be used in QCAT. More information on how to access data in ECOTOX is provided in the following screen capture section.

4. The United Nation's Screening Information Datasets (SIDS), if available.

   UNEP collects hazard information on a number of chemicals of concern and publishes the information collected and reviewed in SIDS. SIDS separates the hazard information into specific sections and the section on Environmental Fate may contain information such as BCFs, Bioaccumulation Factors (BAF) or log K_{ow} (the octanol water coefficient that reports the level of water solubility and is used as a surrogate for bioaccumulation) that can be compared against the Technical Criteria in Appendix 8 and used in QCAT to assign a level of concern. More information will be provided in the following screen-capture section.

5. Canadian Environmental Protection Agency Domestic Substances List (DSL), Bioaccumulative and inherently Toxic chemical (BiT).

   CEPA evaluated chemicals produced or imported into Canada, the DSL, for hazard concerns and published their results in both a database and in Excel spreadsheets for specific criteria. One spreadsheet lists the chemicals that are bioaccumulative and inherently toxic to human health and the environment, abbreviated BiT. Presence on this list is used by QCAT to assign a level of concern.

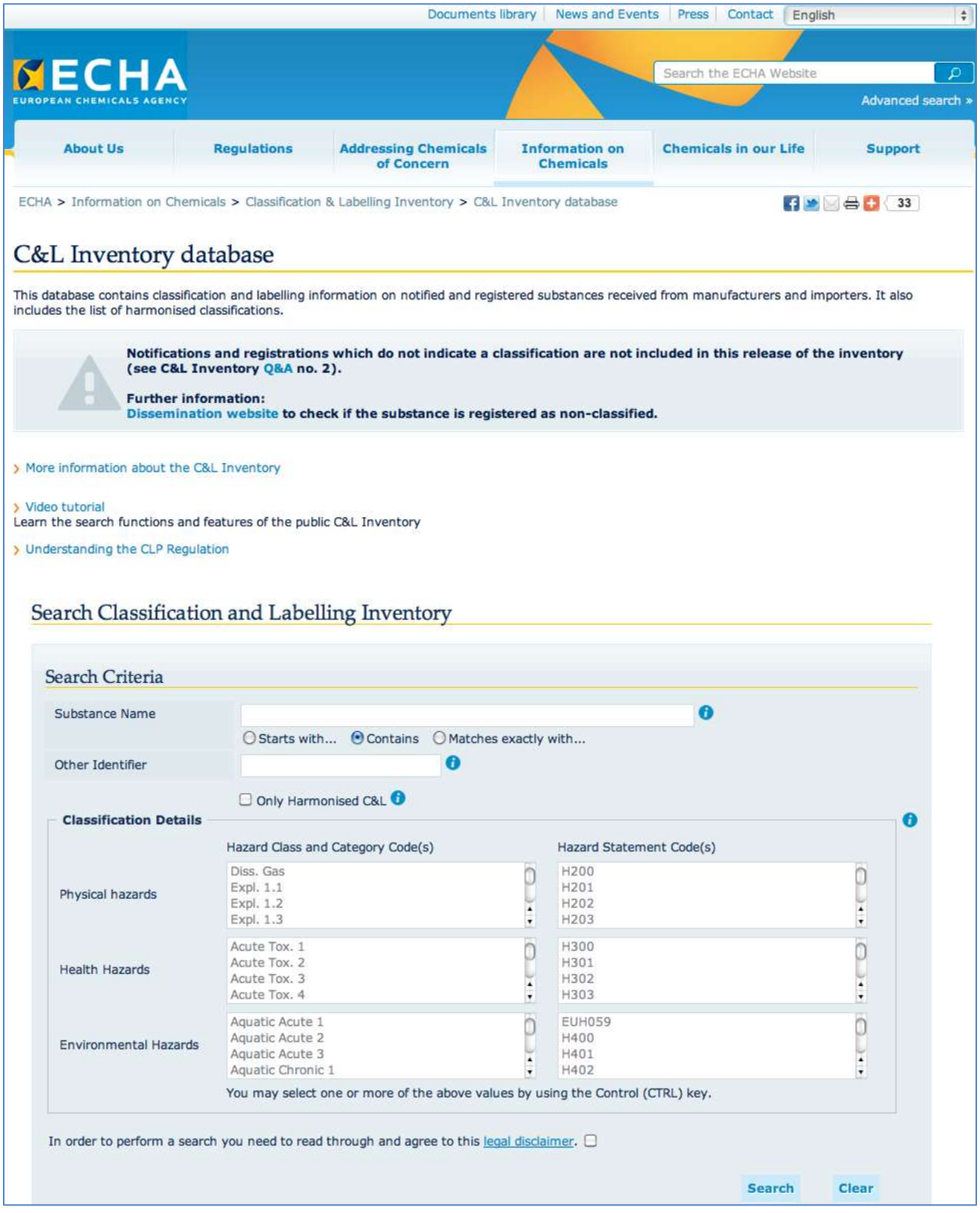
Examples of Data from Individual Databases used in Appendix 2

European Chemical Agency (ECHA) Classification and Labeling Database:

The Classification and Labeling Database (C&L Database) is the result of the European Chemical Agency (ECHA) compiling all of the classification and labeling data submitted during chemical registration as required under REACH. ECHA made no attempt to review the submittals and there may be errors within the database. Since there is no incentive for a manufacturer to report a problem for a chemical if none exists, this database is potentially a good source for hazard data for chemicals that have been identified as containing some level of concern.

As the C&L Database has not been reviewed, there is less guarantee that chemicals in the database are correctly evaluated and there may be chemicals with hazard concerns that are not identified. QCAT users may wish to evaluate the information in this database for any data gaps remaining after evaluating other Step II sources. If a chemical is identified as a concern for any of the remaining hazard endpoints, the results can be used to define the degree of hazard involved. If there are any conflicts between this database and other Step II sources, the other sources may be given greater emphasis as this database has not been peer reviewed or audited.

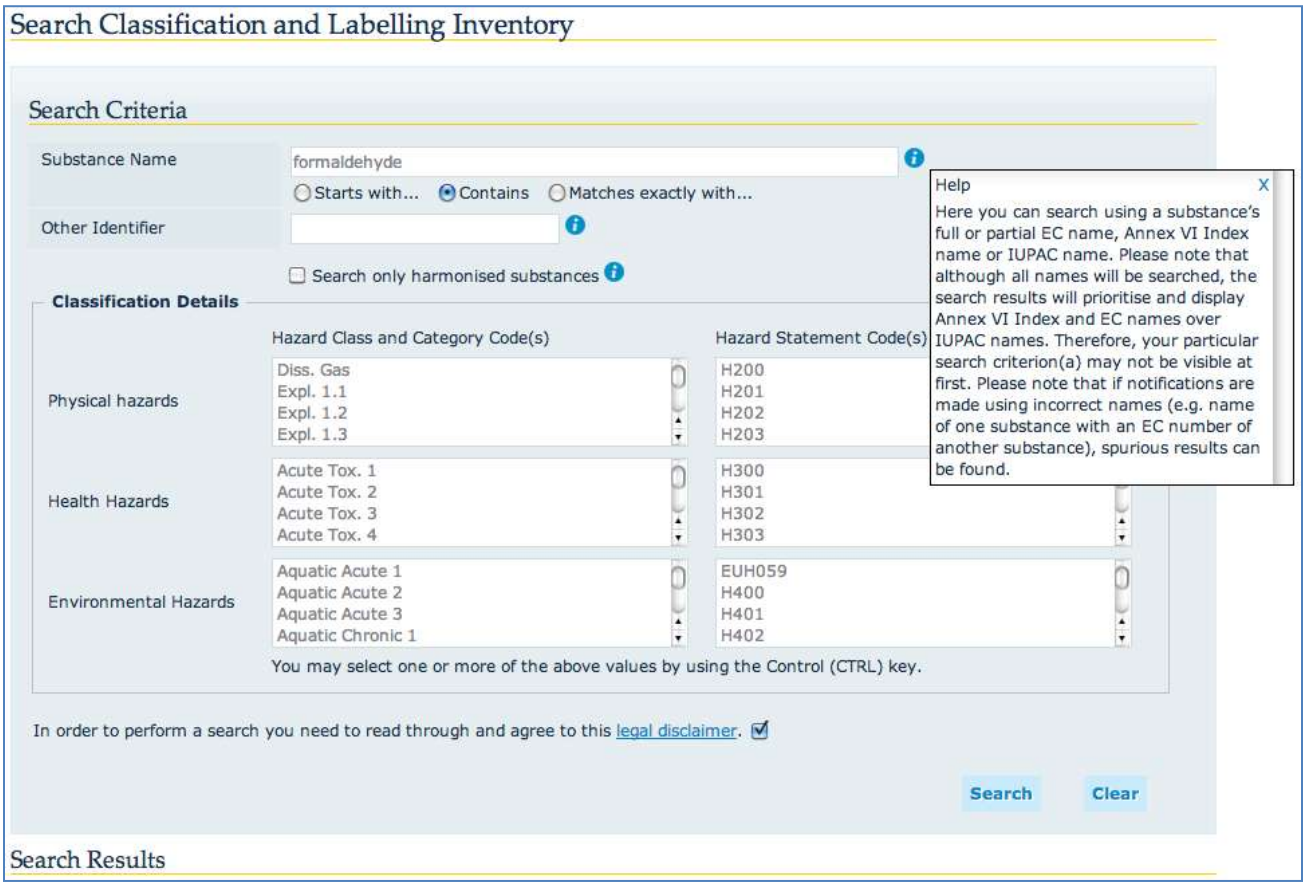
Access to the C&L database is straightforward. The opening page appears as:



The QCAT user can search for information in several ways but the recommended method is to insert the CAS number in the line called ‘Other Identifier.’ The user MUST also check the small box at the end of

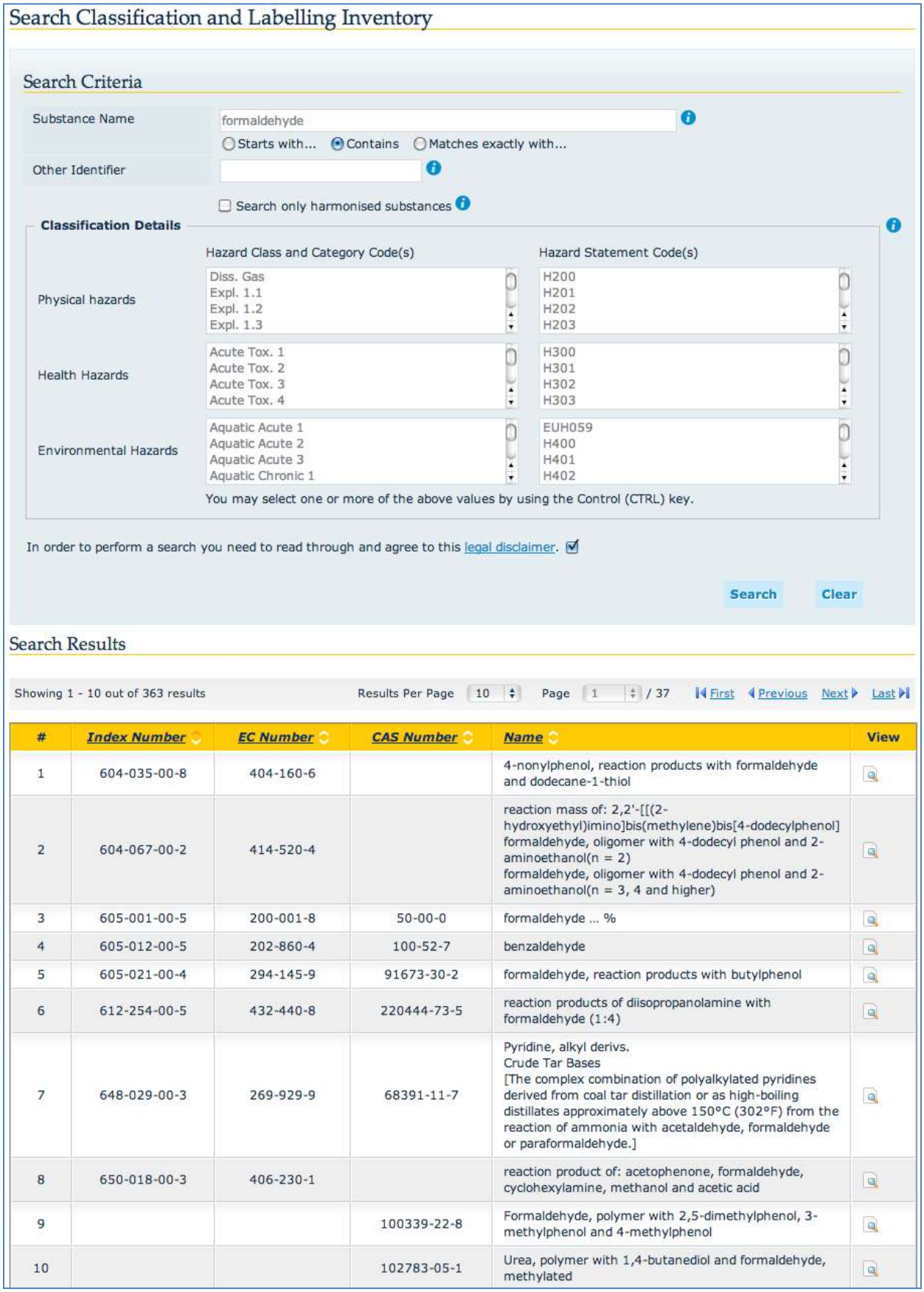
the sentence ‘In order to perform a search you need to read through and agree to this legal disclaimer.’ Without checking this box, the user cannot proceed to the actual data.

’Formaldehyde’ for example, is typed into the first box ‘Substance Name’ and the ‘Search’ button is pressed. If there are any questions, the database contains help functions imbedded in the blue circle with ‘i’ for ‘information’ in the center. For example, the help information for ‘Substance Name’ is show below:



The database will conduct a search for the requested information by pressing the ‘Search’ button and identify any information that meets the desired criteria.

The search on the word ‘formaldehyde’ yields the following:



Search Classification and Labelling Inventory

Search Criteria

Substance Name: formaldehyde

Starts with... Contains Matches exactly with...

Other Identifier:

Search only harmonised substances

Classification Details

	Hazard Class and Category Code(s)	Hazard Statement Code(s)
Physical hazards	Diss. Gas Expl. 1.1 Expl. 1.2 Expl. 1.3	H200 H201 H202 H203
Health Hazards	Acute Tox. 1 Acute Tox. 2 Acute Tox. 3 Acute Tox. 4	H300 H301 H302 H303
Environmental Hazards	Aquatic Acute 1 Aquatic Acute 2 Aquatic Acute 3 Aquatic Chronic 1	EUH059 H400 H401 H402

You may select one or more of the above values by using the Control (CTRL) key.

In order to perform a search you need to read through and agree to this legal disclaimer.

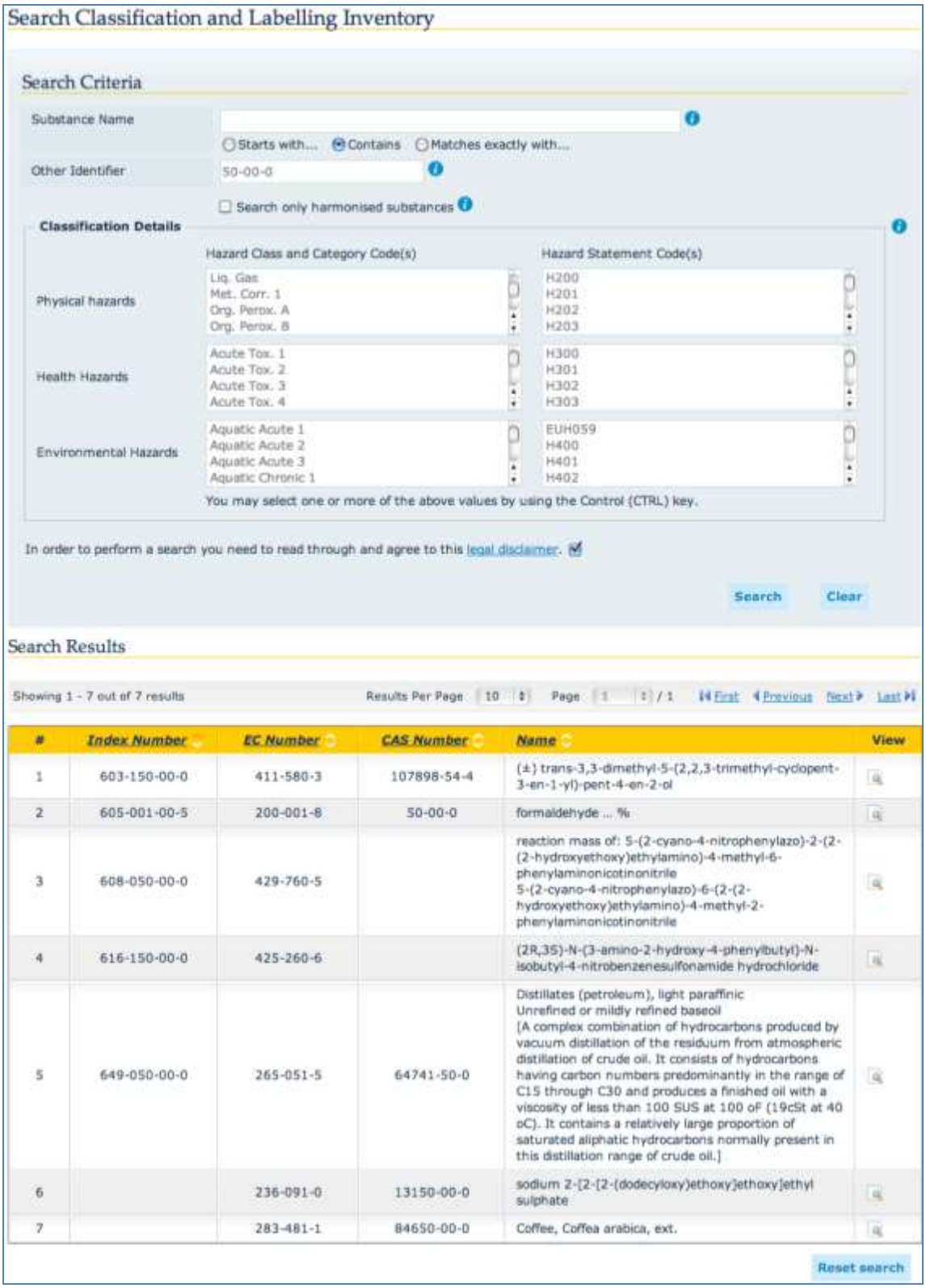
Search Clear

Search Results

Showing 1 - 10 out of 363 results Results Per Page 10 Page 1 / 37 First Previous Next Last

#	Index Number	EC Number	CAS Number	Name	View
1	604-035-00-8	404-160-6		4-nonylphenol, reaction products with formaldehyde and dodecane-1-thiol	
2	604-067-00-2	414-520-4		reaction mass of: 2,2'-[[(2-hydroxyethyl)imino]bis(methylene)bis[4-dodecylphenol] formaldehyde, oligomer with 4-dodecyl phenol and 2-aminoethanol(n = 2) formaldehyde, oligomer with 4-dodecyl phenol and 2-aminoethanol(n = 3, 4 and higher)	
3	605-001-00-5	200-001-8	50-00-0	formaldehyde ... %	
4	605-012-00-5	202-860-4	100-52-7	benzaldehyde	
5	605-021-00-4	294-145-9	91673-30-2	formaldehyde, reaction products with butylphenol	
6	612-254-00-5	432-440-8	220444-73-5	reaction products of diisopropanolamine with formaldehyde (1:4)	
7	648-029-00-3	269-929-9	68391-11-7	Pyridine, alkyl derivs. Crude Tar Bases [The complex combination of polyalkylated pyridines derived from coal tar distillation or as high-boiling distillates approximately above 150°C (302°F) from the reaction of ammonia with acetaldehyde, formaldehyde or paraformaldehyde.]	
8	650-018-00-3	406-230-1		reaction product of: acetophenone, formaldehyde, cyclohexylamine, methanol and acetic acid	
9			100339-22-8	Formaldehyde, polymer with 2,5-dimethylphenol, 3-methylphenol and 4-methylphenol	
10			102783-05-1	Urea, polymer with 1,4-butanediol and formaldehyde, methylated	

As with Pharos, any listing containing the term ‘formaldehyde’ appears and it is difficult to identify the chemical of interest. The assessor should use a unique identifier such as the CAS number to find data on a specific chemical. Instead of searching for the term ‘formaldehyde,’ the assessor enters the CAS number (50-00-0) in the second line labeled ‘Other Identifier’ and searching yields the following results: Although all listings containing ’50-00-0’ are shown, the listing for formaldehyde is clear. The QCAT



Search Classification and Labelling Inventory

Search Criteria

Substance Name

Starts with... Contains Matches exactly with...

Other Identifier 50-00-0

Search only harmonised substances

Classification Details

	Hazard Class and Category Code(s)	Hazard Statement Code(s)
Physical hazards	Liq. Gas Met. Corr. 1 Org. Perox. A Org. Perox. B	H200 H201 H202 H203
Health Hazards	Acute Tox. 1 Acute Tox. 2 Acute Tox. 3 Acute Tox. 4	H300 H301 H302 H303
Environmental Hazards	Aquatic Acute 1 Aquatic Acute 2 Aquatic Acute 3 Aquatic Chronic 1	EUH059 H400 H401 H402

You may select one or more of the above values by using the Control (CTRL) key.

In order to perform a search you need to read through and agree to this legal disclaimer.

Search Clear

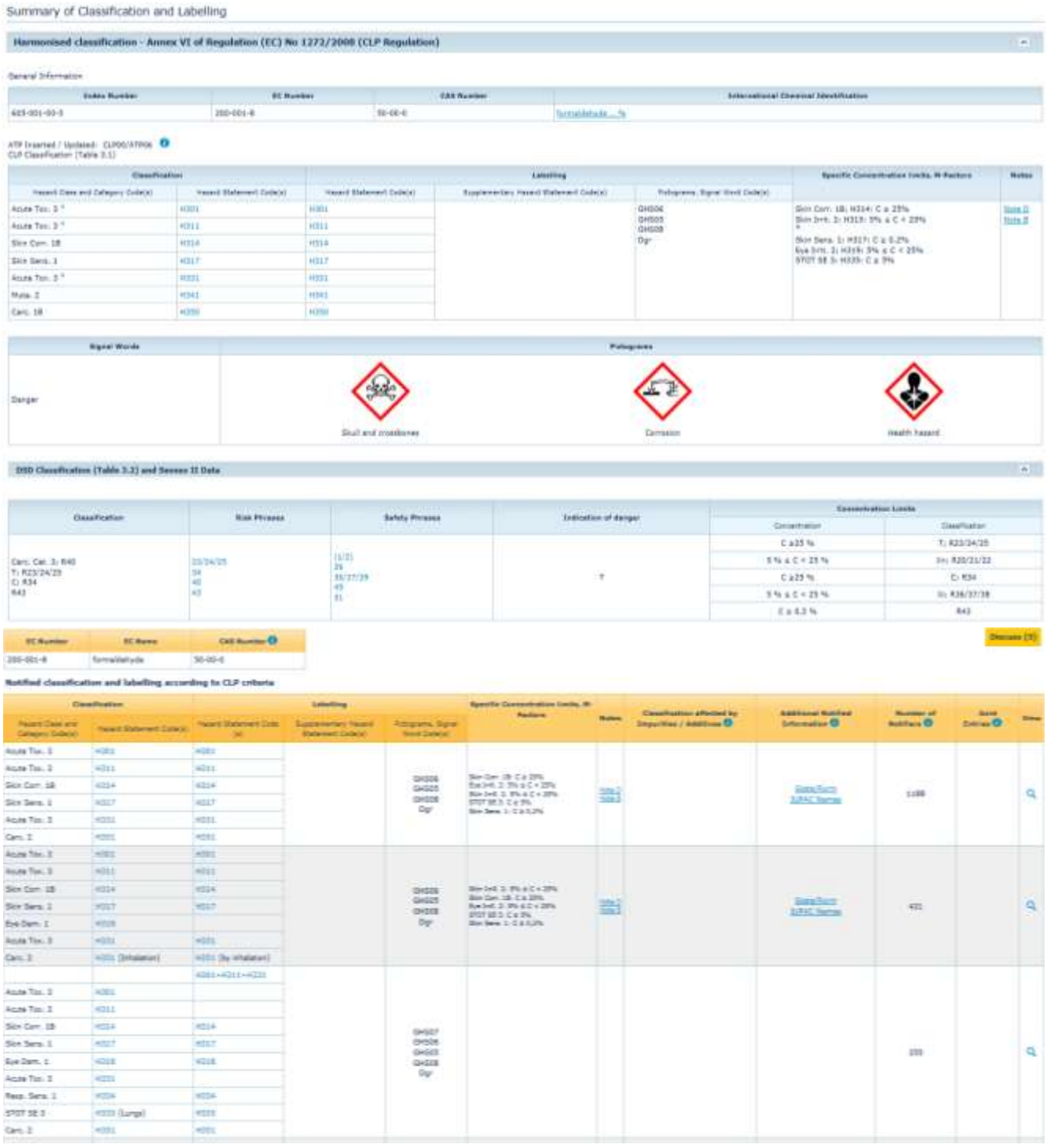
Search Results

Showing 1 - 7 out of 7 results Results Per Page 10 Page 1 / 1 First Previous Next Last

#	Index Number	EC Number	CAS Number	Name	View
1	603-150-00-0	411-580-3	107898-54-4	(±) trans-3,3-dimethyl-5-(2,2,3-trimethyl-cyclopent-3-en-1-yl)-pent-4-en-2-ol	
2	605-001-00-5	200-001-8	50-00-0	formaldehyde ... %	
3	608-050-00-0	429-760-5		reaction mass of: 5-(2-cyano-4-nitrophenylazo)-2-(2-(2-hydroxyethoxy)ethylamino)-4-methyl-6-phenylaminonicotinonitrile 5-(2-cyano-4-nitrophenylazo)-6-(2-(2-hydroxyethoxy)ethylamino)-4-methyl-2-phenylaminonicotinonitrile	
4	616-150-00-0	425-260-6		(2R,3S)-N-(3-amino-2-hydroxy-4-phenylbutyl)-N-isobutyl-4-nitrobenzenesulfonamide hydrochloride	
5	649-050-00-0	265-051-5	64741-50-0	Distillates (petroleum), light paraffinic Unrefined or mildly refined baseoil [A complex combination of hydrocarbons produced by vacuum distillation of the residuum from atmospheric distillation of crude oil. It consists of hydrocarbons having carbon numbers predominantly in the range of C15 through C30 and produces a finished oil with a viscosity of less than 100 SUS at 100 oF (19cSt at 40 oC). It contains a relatively large proportion of saturated aliphatic hydrocarbons normally present in this distillation range of crude oil.]	
6		236-091-0	13150-00-0	sodium 2-[2-[2-(dodecyloxy)ethoxy]ethoxy]ethyl sulphate	
7		283-481-1	84650-00-0	Coffee, Coffea arabica, ext.	

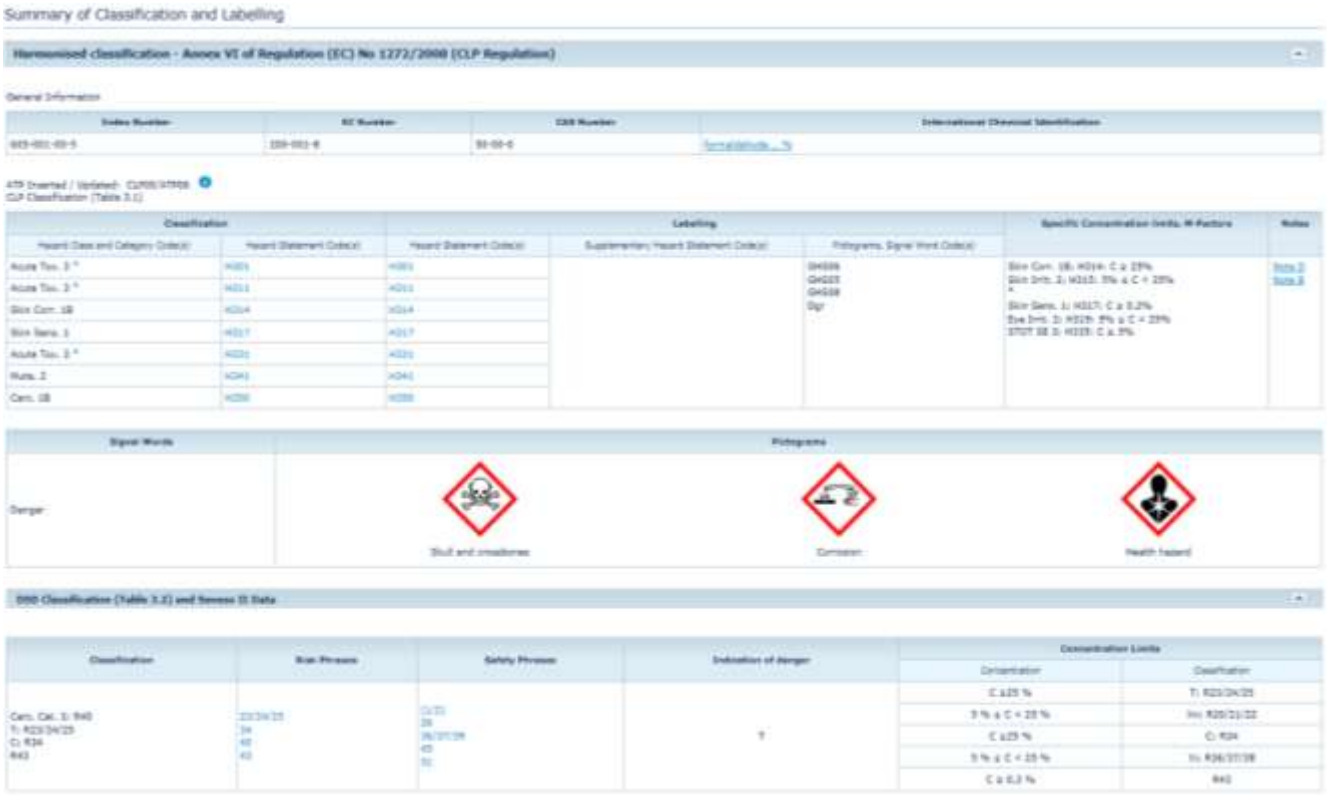
Reset search

user clicks on the file in the ‘View’ column that coincides with the desired CAS number for formaldehyde (50-00-0). Clicking on the link in ‘View’ causes the following to be displayed:



The above is only a partial list of all of the results. The assessor can identify the hazard codes associated with formaldehyde using either a weight of evidence or a most conservative approach.

The top half of the report provides a summary of the hazard codes and other pertinent information for formaldehyde:


Summary of Classification and Labelling

Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)

General Information

Index Number	EC Number	CAS Number	International Chemical Identification
605-001-00-5	200-001-8	50-00-0	formaldehyde ... %

ATP Inserted / Updated: CLP00/ATP00
CLP Classification [Table 3.1]

Classification		Labelling			Specific Concentration Limits, M-Factors	Notes
Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement Code(s)	Supplementary Hazard Statement Code(s)	Pictograms, Signal Word Code(s)		
Acute Tox. 3 *	H301	H301		GHS06 GHS05 GHS08 Dgr	Skin Corr. 1B; H314: C ≥ 25% Skin Irrit. 2; H315: 5% ≤ C < 25% * Skin Sens. 1; H317: C ≥ 0.2% Eye Irrit. 2; H319: 5% ≤ C < 25% STOT SE 3; H335: C ≥ 5%	Note 2 Note B
Acute Tox. 3 *	H311	H311				
Skin Corr. 1B	H314	H314				
Skin Sens. 1	H317	H317				
Acute Tox. 3 *	H331	H331				
Muta. 2	H341	H341				
Carc. 1B	H350	H350				

Signal Words	Pictograms
Danger	

Skull and crossbones | Corrosion | Health hazard

DSD Classification (Table 3.2) and Annex II Data

Classification	Risk Phrases	Safety Phrases	Indication of danger	Concentration Limits	
				Orientation	Classification
Carc. Cat. 3; R40 T; R23/24/25 C; R34 R43	23/24/25 34 40 43	(1/2) 28 36/37/39 45 51	T	C ≥ 25 %	T; R23/24/25
				5 % ≤ C < 25 %	Xn; R20/21/22
				C ≥ 25 %	C; R34
				5 % ≤ C < 25 %	Xi; R36/37/38
				C ≥ 0.2 %	R43

The database provides hazard and risk codes for acute toxicity and carcinogenicity. If these hazard endpoints have been satisfied using data from Step I sources, this information may not be useful. As the database contains information on a wider range of chemicals than those identified in Step I sources, information on other chemicals will prove more useful. This example, however, indicates the type of information available and how it is displayed.

The second half of the report provides information on specific registration dossiers provided to the European Chemicals Agency as required by REACH:

If there are any questions about the source of the information, the ‘View’ column at the end provides a copy of the report providing the information reported. This information is unlikely to be of interest to the standard QCAT user but is available if any questions arise.

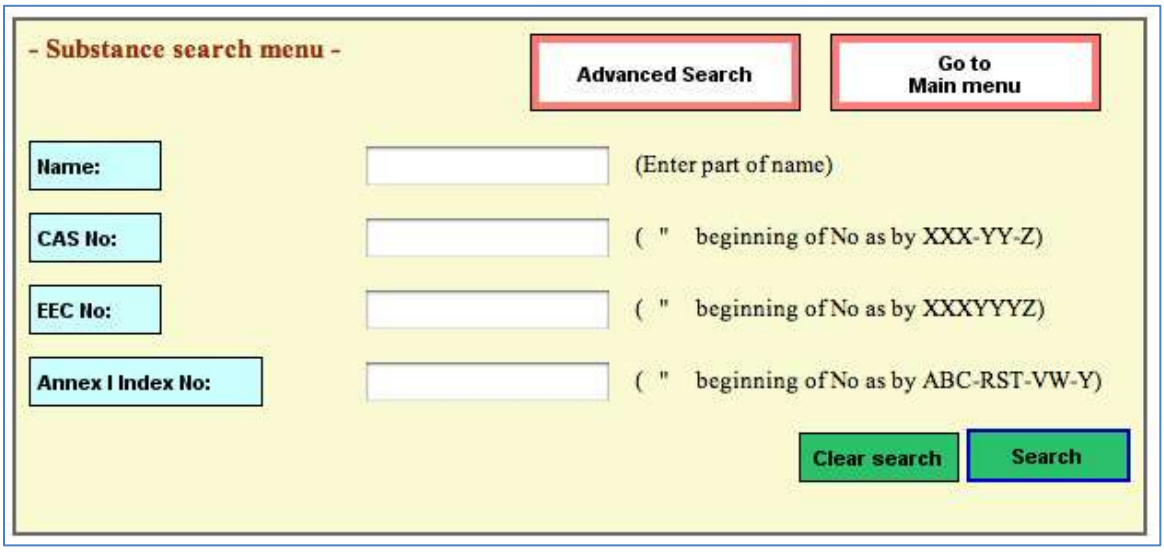
In addition, the database provides other data not useful to most QCAT users, specifically hazard criteria like Skin Sensitivity and Skin Corrosion not included in a QCAT assessment. It is mentioned here, however, so the QCAT user understands what is being displayed and whether or not it would be useful in a QCAT assessment.

KEMI Swedish Chemicals Agency N-Class Database on Environmental Hazards:

The Swedish Chemicals Agency in collaboration with the European Chemicals Bureau has collected information on the environmental hazard classification for approximately 7,000 compounds and has provided this information in its N-Class Database.

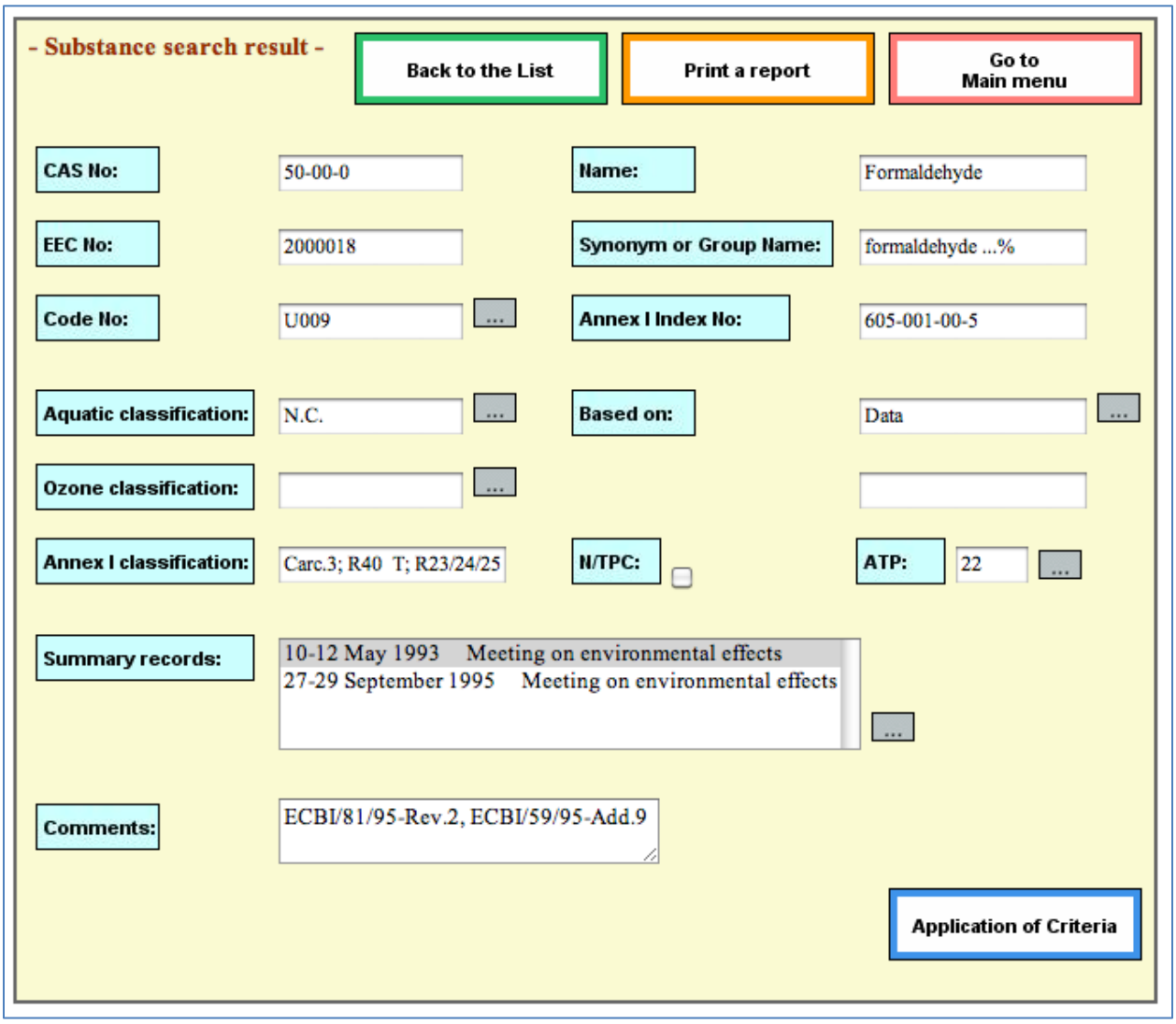
The introductory page for the database appears as:

A simple 'Substance search' sends you to a window where the name, CAS number, or other defining information can be entered:



Using formaldehyde (CAS 50-00-0) as an example, the database will then display whether or not the compound is found in the database:

By selecting the information highlighted in blue, the data are displayed:

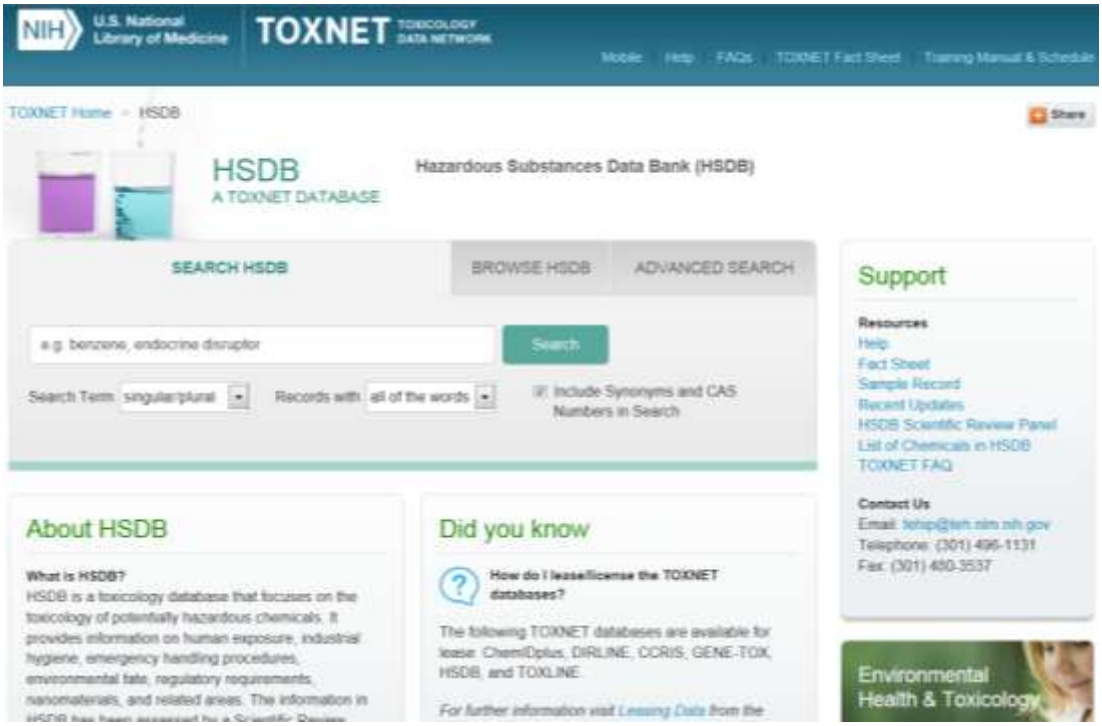


The GHS classification is provided in the box labeled 'Aquatic Classification.' Note that that additional information on other potential toxicity concerns may also be displayed in the box labeled 'Annex I classification.' This source of aquatic information may prove useful to complete the QCAT.

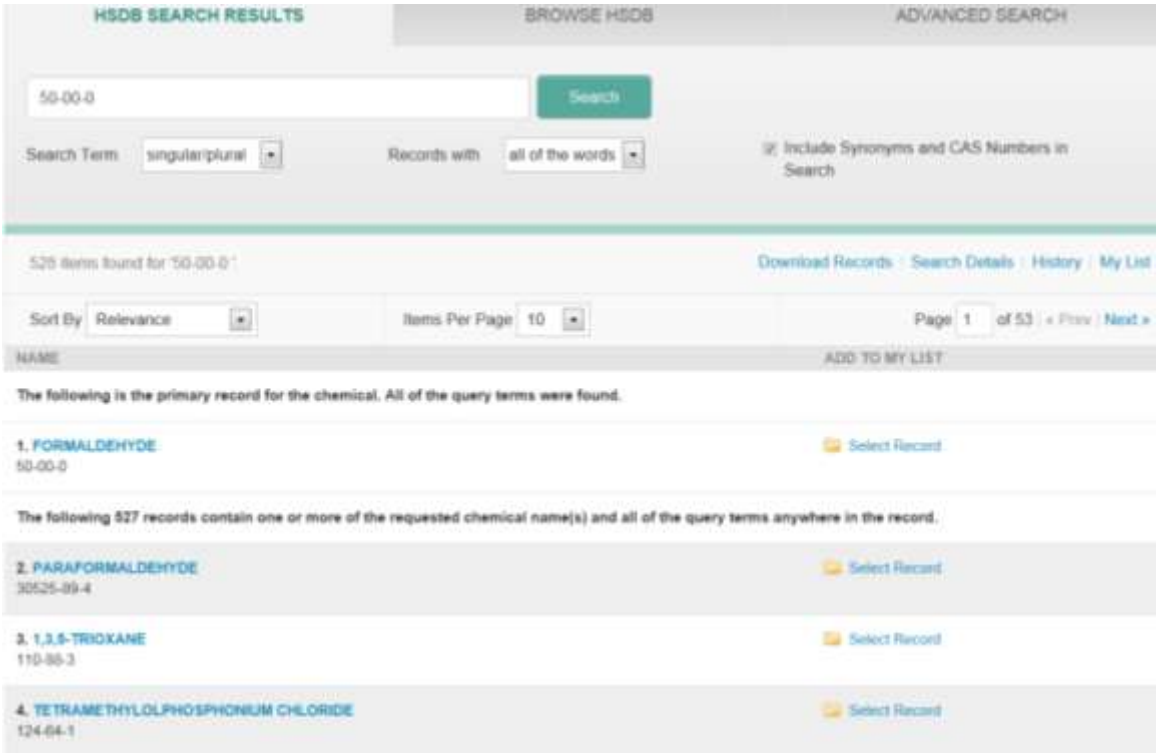
Hazardous Substances Databank (HSDB):

The HSDB contains considerable information on the toxicity of specific chemicals. This includes excerpts from specific sources and detailed information on the specific chemical impacts. HSDB also displays specific toxicity results, which have undergone technical review and conclusions on certain toxicity criteria, which will be of use in a QCAT evaluation. The three primary toxicity criteria of interest are acute mammalian toxicity, acute aquatic toxicity, and carcinogenicity. Information may be available on other toxicity criteria included in the QCAT; however, these data vary widely from chemical to chemical and should be used with caution.

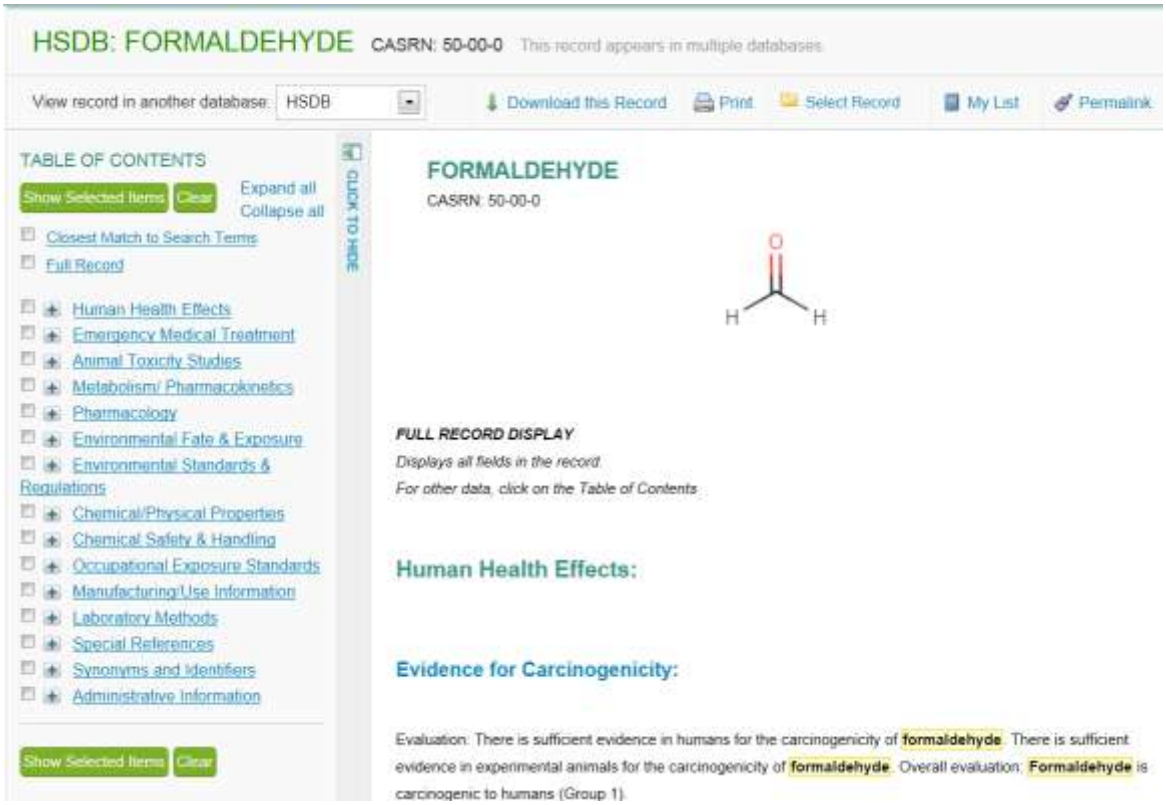
The following is HSDB's initial page:



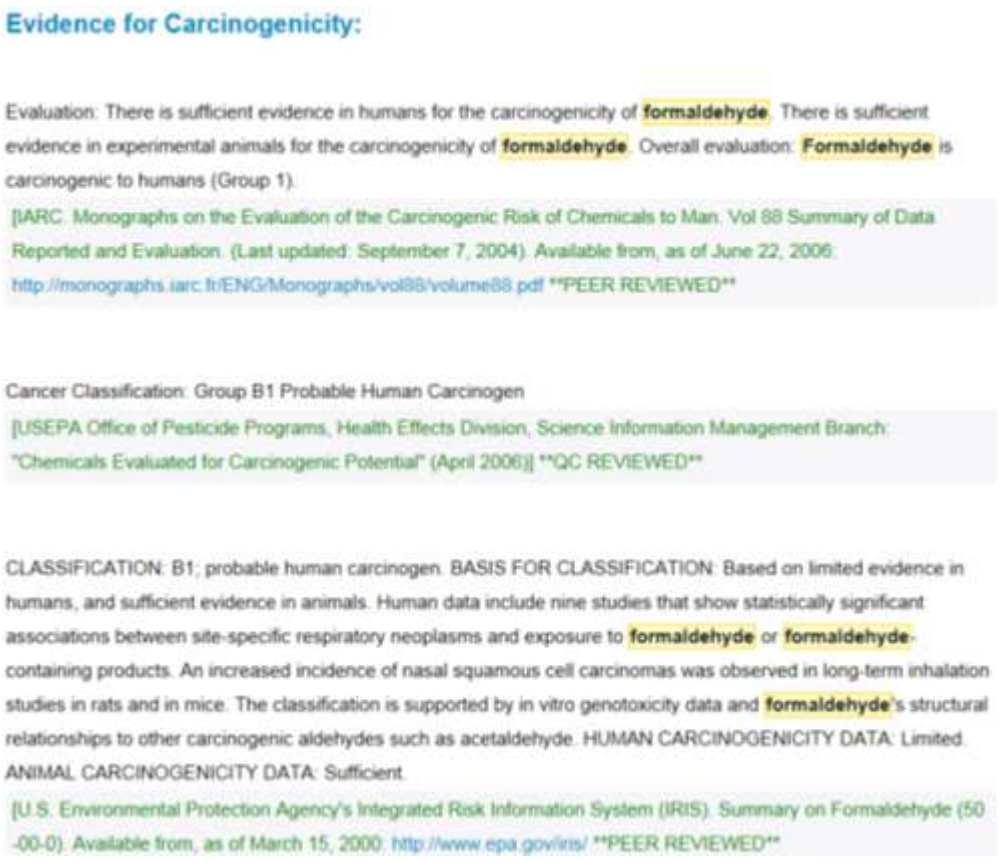
As an example, the CAS number for formaldehyde (50-00-0) is entered into the 'Search HSDB' and the 'Search' button pressed.



Clicking on the blue ‘Formaldehyde’ takes the assessor directly to available data in the HSDB.

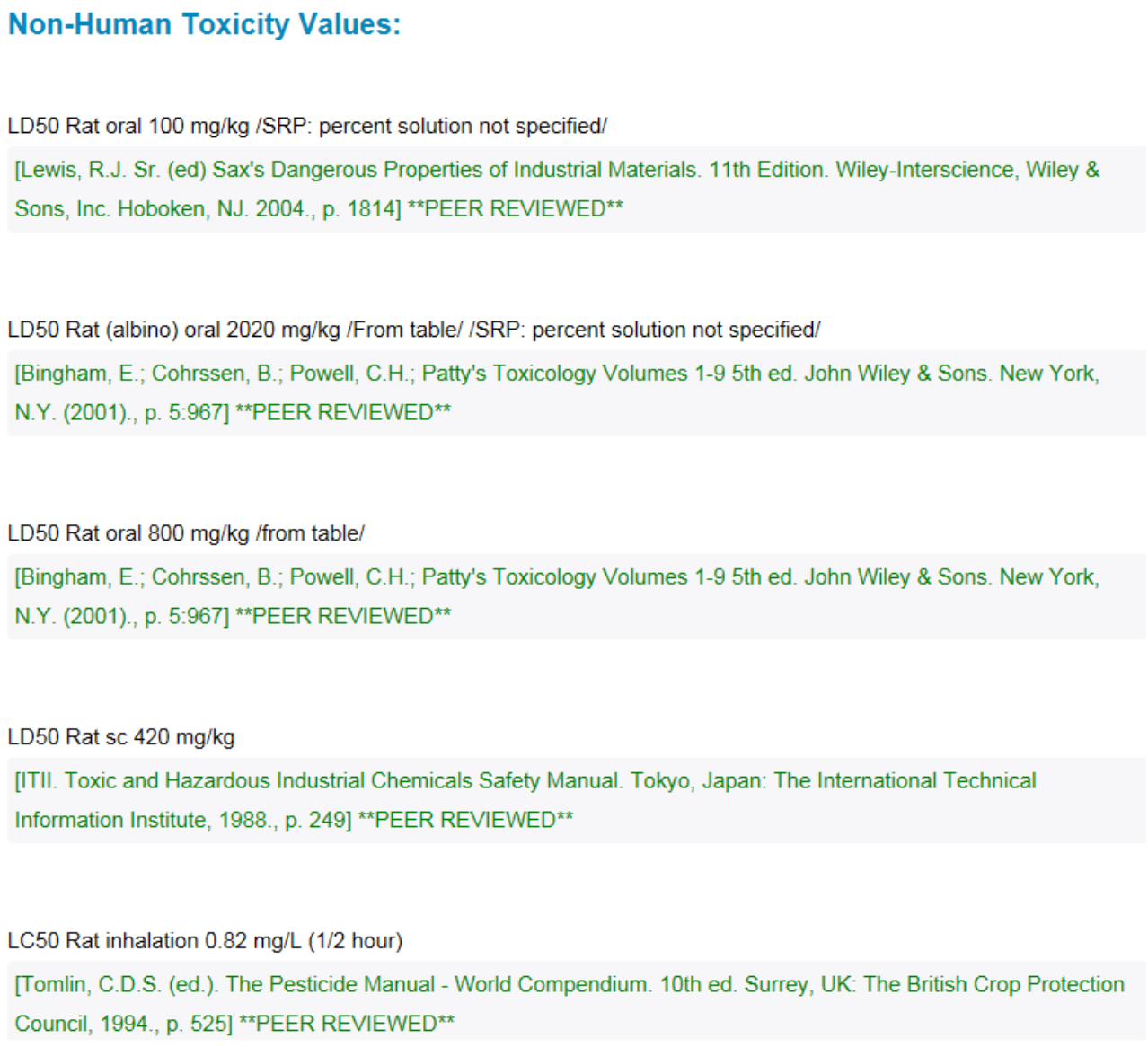


Clicking on the blue ‘Human Health Effects’ line on the left identifies human health data, a portion of which is shown below:



The Table of Contents on the left displays various pages of the report. Data in three specific pages will be discussed in the subsequent sections.

Acute Mammalian Toxicity: Under 'Animal Toxicity Studies', clicking on 'Non-Human Toxicity Values' provides acute mammalian toxicity values of interest for the QCAT evaluation:



Non-Human Toxicity Values:

LD50 Rat oral 100 mg/kg /SRP: percent solution not specified/

[Lewis, R.J. Sr. (ed) Sax's Dangerous Properties of Industrial Materials. 11th Edition. Wiley-Interscience, Wiley & Sons, Inc. Hoboken, NJ. 2004., p. 1814] **PEER REVIEWED**

LD50 Rat (albino) oral 2020 mg/kg /From table/ /SRP: percent solution not specified/

[Bingham, E.; Cohrssen, B.; Powell, C.H.; Patty's Toxicology Volumes 1-9 5th ed. John Wiley & Sons. New York, N.Y. (2001)., p. 5:967] **PEER REVIEWED**

LD50 Rat oral 800 mg/kg /from table/

[Bingham, E.; Cohrssen, B.; Powell, C.H.; Patty's Toxicology Volumes 1-9 5th ed. John Wiley & Sons. New York, N.Y. (2001)., p. 5:967] **PEER REVIEWED**

LD50 Rat sc 420 mg/kg

[ITII. Toxic and Hazardous Industrial Chemicals Safety Manual. Tokyo, Japan: The International Technical Information Institute, 1988., p. 249] **PEER REVIEWED**

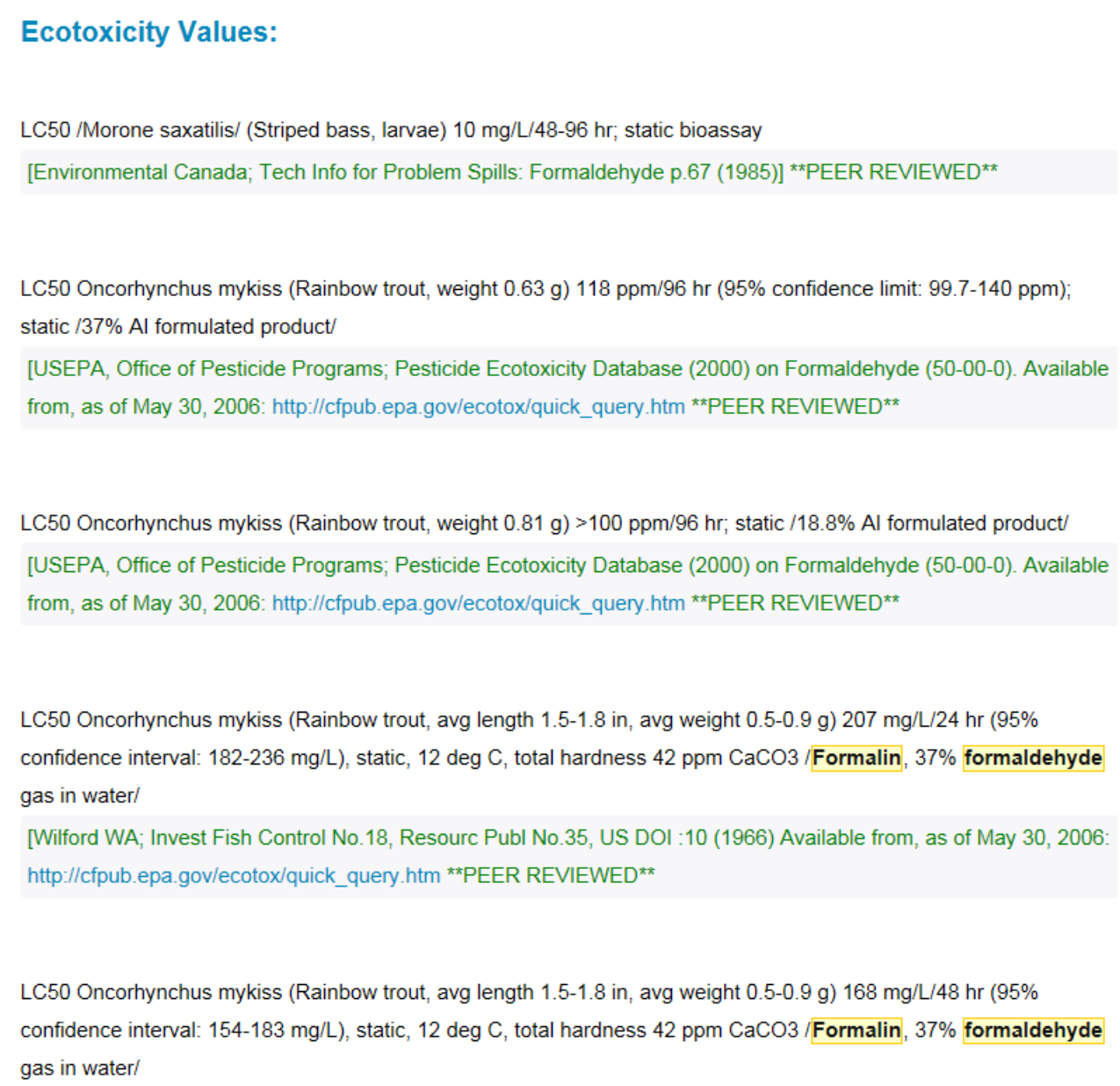
LC50 Rat inhalation 0.82 mg/L (1/2 hour)

[Tomlin, C.D.S. (ed.). The Pesticide Manual - World Compendium. 10th ed. Surrey, UK: The British Crop Protection Council, 1994., p. 525] **PEER REVIEWED**

Note: This screen capture presents only a portion of the data available and is representative of what the HSDB contains

For the purposes of the QCAT, the LC_{50} and LD_{50} toxicity values provided are compared with the Technical Criteria in Appendix 8 to determine the level of concern.

Acute aquatic toxicity: Under 'Animal Toxicity Studies', clicking on 'Ecotoxicity values' provides acute aquatic toxicity values of interest for the QCAT evaluation:



Ecotoxicity Values:

LC50 /Morone saxatilis/ (Striped bass, larvae) 10 mg/L/48-96 hr; static bioassay

[Environmental Canada; Tech Info for Problem Spills: Formaldehyde p.67 (1985)] **PEER REVIEWED**

LC50 Oncorhynchus mykiss (Rainbow trout, weight 0.63 g) 118 ppm/96 hr (95% confidence limit: 99.7-140 ppm); static /37% AI formulated product/

[USEPA, Office of Pesticide Programs; Pesticide Ecotoxicity Database (2000) on Formaldehyde (50-00-0). Available from, as of May 30, 2006: http://cfpub.epa.gov/ecotox/quick_query.htm **PEER REVIEWED**

LC50 Oncorhynchus mykiss (Rainbow trout, weight 0.81 g) >100 ppm/96 hr; static /18.8% AI formulated product/

[USEPA, Office of Pesticide Programs; Pesticide Ecotoxicity Database (2000) on Formaldehyde (50-00-0). Available from, as of May 30, 2006: http://cfpub.epa.gov/ecotox/quick_query.htm **PEER REVIEWED**

LC50 Oncorhynchus mykiss (Rainbow trout, avg length 1.5-1.8 in, avg weight 0.5-0.9 g) 207 mg/L/24 hr (95% confidence interval: 182-236 mg/L), static, 12 deg C, total hardness 42 ppm CaCO3 /**Formalin**, 37% **formaldehyde** gas in water/

[Wilford WA; Invest Fish Control No.18, Resourc Publ No.35, US DOI :10 (1966) Available from, as of May 30, 2006: http://cfpub.epa.gov/ecotox/quick_query.htm **PEER REVIEWED**

LC50 Oncorhynchus mykiss (Rainbow trout, avg length 1.5-1.8 in, avg weight 0.5-0.9 g) 168 mg/L/48 hr (95% confidence interval: 154-183 mg/L), static, 12 deg C, total hardness 42 ppm CaCO3 /**Formalin**, 37% **formaldehyde** gas in water/

Note: This screen capture presents only a portion of the data available and is representative of what the HSDB contains

For the purposes of ecotoxicity review, LC_{50} fish data will be evaluated using the process established within Washington State's Dangerous Waste Regulations (WAC 173-303):

> *'Fish LC_{50} data must be derived from an exposure period greater than or equal to twenty-four hours. A hierarchy of species LC_{50} data should be used that includes (in decreasing order of preference) salmonids, fathead minnows, and other fish species.'*

For other ecotoxicity data, the species with the most data are assumed to be indicative of the chemical's toxic effects. This information can be interpreted using the Technical Criteria for Acute Aquatic Toxicity in Appendix 8 and directly applied to the QCAT ranking criteria.

Carcinogenicity: Where available, the HSDB also provides an assessment of whether or not a chemical is a known or suspected carcinogen. Much of the information in this assessment is pulled from other sources used in the Step I analysis and may be duplicative. However, the HSDB does include other sources that may be useful in a Step II evaluation. For example, the carcinogenicity information on formaldehyde appears under 'Human Health Effects'. Clicking on 'Evidence for carcinogenicity' provides the following:

Evidence for Carcinogenicity:

Evaluation: There is sufficient evidence in humans for the carcinogenicity of **formaldehyde**. There is sufficient evidence in experimental animals for the carcinogenicity of **formaldehyde**. Overall evaluation: **Formaldehyde** is carcinogenic to humans (Group 1).

[IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man. Vol 88 Summary of Data Reported and Evaluation. (Last updated: September 7, 2004). Available from, as of June 22, 2006: http://monographs.iarc.fr/ENG/Monographs/vol88/volume88.pdf **PEER REVIEWED**

Cancer Classification: Group B1 Probable Human Carcinogen

[USEPA Office of Pesticide Programs, Health Effects Division, Science Information Management Branch: "Chemicals Evaluated for Carcinogenic Potential" (April 2006)] **QC REVIEWED**

CLASSIFICATION: B1; probable human carcinogen. BASIS FOR CLASSIFICATION: Based on limited evidence in humans, and sufficient evidence in animals. Human data include nine studies that show statistically significant associations between site-specific respiratory neoplasms and exposure to **formaldehyde** or **formaldehyde**-containing products. An increased incidence of nasal squamous cell carcinomas was observed in long-term inhalation studies in rats and in mice. The classification is supported by in vitro genotoxicity data and **formaldehyde**'s structural relationships to other carcinogenic aldehydes such as acetaldehyde. HUMAN CARCINOGENICITY DATA: Limited. ANIMAL CARCINOGENICITY DATA: Sufficient.

[U.S. Environmental Protection Agency's Integrated Risk Information System (IRIS). Summary on Formaldehyde (50-00-0). Available from, as of March 15, 2000: http://www.epa.gov/iris/ **PEER REVIEWED**

A2; Suspected human carcinogen.

[American Conference of Governmental Industrial Hygienists TLVs and BEIs. Threshold Limit Values for Chemical

Three out of the four data points identified above are Step I sources although the conclusion from the American Conference of Governmental Industrial Hygienists TLVS and BEIs is not. This source was reviewed by experts and deemed worthy for inclusion. Additional sources like this might prove useful for other chemicals not identified in Step I sources.

Searching HSDB: An easier method for locating information in the HSDB is to click on the complete record for the chemical being evaluated. This record can then be searched (by pressing the Control key

and ‘F’ simultaneously) to search out pertinent information for each hazard criteria. Ecology has found the following keywords (or any portion thereof) useful in evaluating data contained in the HSDB:

- Carcinogenicity
- Mutagenicity
- Genotoxicity (used to report mutagenicity results)
- Reproduction
- Developmental

The user may use other keywords that assist in this process.

For example, the full HSDB record for formaldehyde was searched for reproductive hazards using just the fragment 'reprod' in the Control F method described above. The following information was located:

```
 0.2.19.2 CHRONIC EXPOSURE
   A)  Allergic contact dermatitis, eczema, and other signs
       have been attributed to formaldehyde sensitivity.
0.2.20 REPRODUCTIVE HAZARDS
  A)  Formaldehyde has not been shown definitely to be
      teratogenic in animals. Formaldehyde probably presents
      little or no risk as a potential human teratogen.
  B)  Menstrual disorders have been reported in women
      occupationally exposed to formaldehyde, but these
      results are controversial. In experimental animal
      studies, some effects on spermatogenesis have been
      reported.
  C)  Occupational exposure at recommended limits is not
      thought to present a reproductive risk. Formaldehyde
      exposure among female hospital workers did not correlate
      with an increase in spontaneous abortion in one study,
      but did correlate in another.
   1)  Low-birthweight children have been reported in female
       workers exposed to urea-formaldehyde resin, but studies
       are inconclusive. Formaldehyde appears to cross the
       placental barrier in mice.
0.2.21 CARCINOGENICITY
 0.2.21.1 IARC CATEGORY
   A)  IARC Carcinogenicity Ratings for CAS50-00-0 (IARC
       Working Group on the Evaluation of Carcinogenic Risks
       to Humans, 2006; IARC Working Group on the Evaluation
       of Carcinogenic Risks to Humans, 2007; IARC Working
       Group on the Evaluation of Carcinogenic Risks to
       Humans, 2010; IARC Working Group on the Evaluation of
       Carcinogenic Risks to Humans, 2010a; IARC Working Group
       on the Evaluation of Carcinogenic Risks to Humans,
       2008; IARC, 2004):
    1)  Not Listed
 0.2.21.2 HUMAN OVERVIEW
```

Information in this area could be used to fill in the box for reproductive toxicity. Specifically:

- Reproductive toxicity: *'Menstrual disorders have been reported in women occupationally exposed…'* and *'… did not correlate with an increase in spontaneous abortion in one study, but did correlate in another.'* and *'Low-birthweight children have been reported in female workers…. but studies are inconclusive… appears to cross the placental barrier in mice.'*

This responds to ‘indication of repro/developmental toxicity’ and would qualify as a ‘moderate’ level of concern.

The same formaldehyde record was searched for information on genotoxicity using the fragment ‘genot’. The following information resulted:

0.2.21.3 ANIMAL OVERVIEW

A) An increased incidence of nasal squamous cell carcinomas was observed in long-term inhalation studies in rats and in mice. The classification of B1 is further supported by in vitro genotoxicity data and formaldehyde's structural relationships to other carcinogenic aldehydes such as acetaldehyde.

0.2.22 GENOTOXICITY

A) Formaldehyde appears to be mutagenic. The basis for its genetic activity is its ability to form cross-links in DNA and proteins.

B) Formaldehyde is a potent genotoxin and has been reported to be active in many short-term genetic tests, including the Ames Salmonella assay and other assays for mutation using bacteria, chromosome aberrations and sister chromatid exchanges in vitro and in vivo, and many assays detecting direct effects on DNA.

This information indicates that formaldehyde has a ‘high’ level of concern for mutagenicity/genotoxicity. Specifically:

- *‘Formaldehyde appears to be mutagenic.’*
- *Formaldehyde is a potent genotoxin and has been reported to be active in many short-term genetic tests….’*

By conducting searches like this, the full HSDB record can be evaluated and information pertinent to assessing specific hazard endpoints can be located. Information may be embedded in the full record and may not be obvious. It is important to remember that this data would only be necessary if mutagenicity/genotoxicity or reproductive toxicity are not covered by a Step I authoritative source.

Registry of Toxic Effects of Chemical Substances (RTECS):

RTECS contains data on several toxicity endpoints, which may be of interest to a GS® evaluation. However, many endpoints require technical expertise to evaluate prior to including in a safer chemical alternatives assessment. For the purposes of the QCAT, the acute mammalian toxicity and tumorigenic/carcinogenicity data may prove useful.

Acute Mammalian Toxicity: The RTECS record for formaldehyde contains the following information for acute toxicity:

ACUTE TOXICITY DATA

Type of Test	Route of Exposure	Species Observed	Dose Data	Toxic Effects	Reference
LD50 - Lethal dose, 50 percent kill	Oral	Rodent - rat	100 mg/kg	Details of toxic effects not reported other than lethal dose value	FCTOD7 Food and Chemical Toxicology. (Pergamon Press Inc., Maxwell House, Fairview Park, Elmsford, NY 10523) V.20- 1982- Volume(issue)/page/year: 26,447,1988
LC50 - Lethal concentration, 50 percent kill	Inhalation	Rodent - rat	203 mg/m3	Peripheral Nerve and Sensation - spastic paralysis with or without sensory change Behavioral - convulsions or effect on seizure threshold Behavioral - excitement	GTPZAB GigienaTruda i Professional'nyeZabolevaniya. Labor Hygiene and Occupational Diseases. (V/O MezhdunarodnayaKniga, 113095 Moscow, USSR) V.1-36, 1957-1992. For publisher information, see MTPEEI Volume(issue)/page/year: 18(2),55,1974

etc……

The RTECS acute toxicity dose data may prove useful in completing a QCAT evaluation.

Tumorigenic/Carcinogenicity: The RTECS record for formaldehyde contains the following information for tumorigenic toxicity:

TUMORIGENIC DATA

Type of Test	Route of Exposure	Species Observed	Dose Data	Toxic Effects	Reference
TDLo - Lowest published toxic dose	Oral	Rodent - rat	109 gm/kg/2Y (continuous)	Tumorigenic - **carcinogenic by RTECS criteria**[16] Gastrointestinal - tumors Blood - leukemia	TIHEEC Toxicology and Industrial Health. (Princeton Scientific Pub. Co., POB 2155, Princeton, NJ 08540) V.1-1985- Volume(issue)/page/year: 5,699,1989

etc…..

The determination of whether or not a chemical is determined as tumorigenic/carcinogenic using RTECS criteria may prove useful in completing a QCAT evaluation.

[16] Emphasis added to show reviewer what information to use for making determination.

Occupational Safety & Health Administration (OSHA) Chemical Database (OCD):

The OCD contains information on the potential exposure concerns related to worker health and safety. Although the acute toxicity information requires considerable technical expertise, the OCD does identify chemicals as potential carcinogens.

The Exposure limits section of the report for formaldehyde contains the following information:

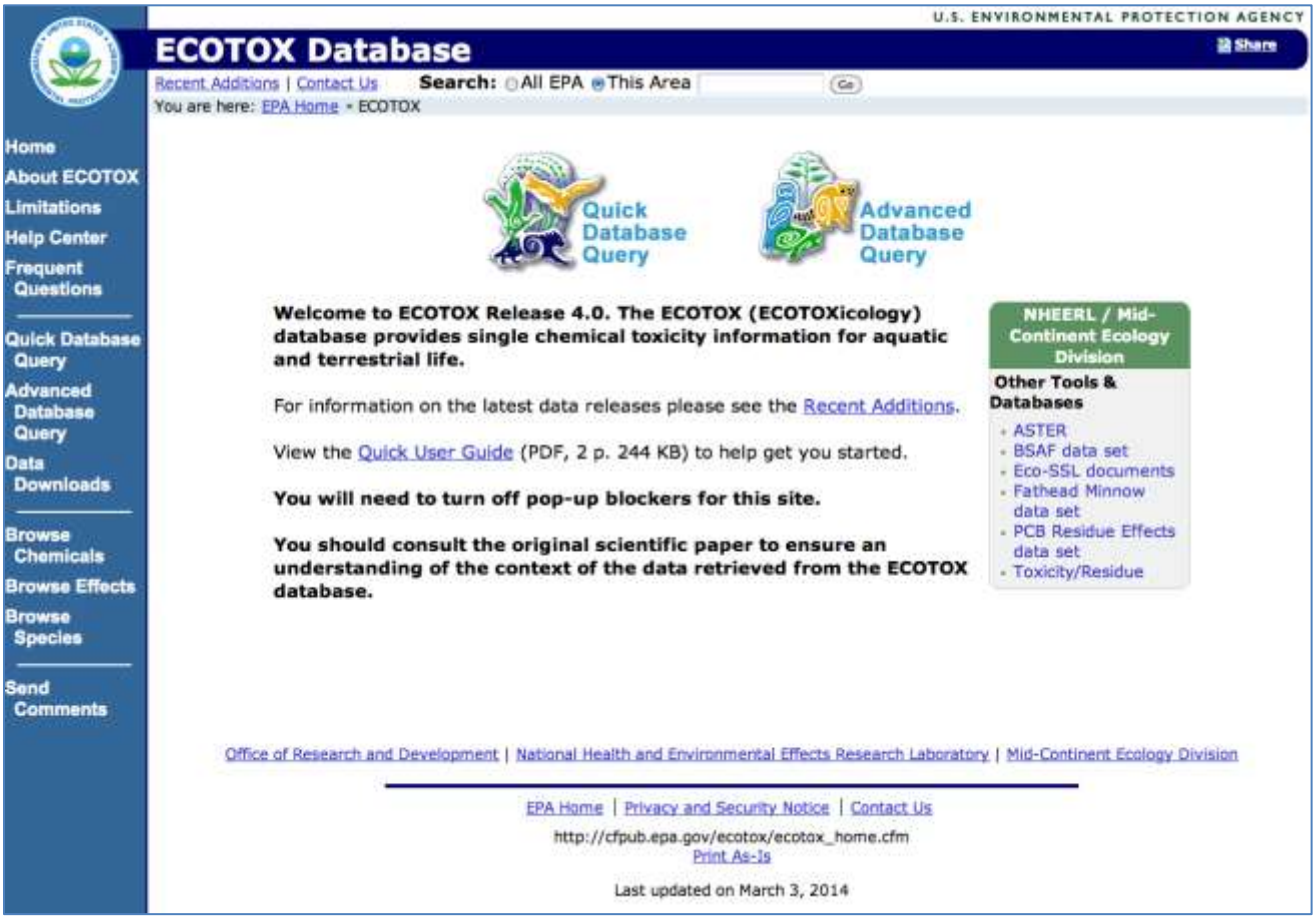
Exposure Limits		
OSHA	**NIOSH**	**Related Information**
PEL-TWA ppm: 0.75	REL-TWA ppm: 0.016	AIHA Emergency Response Planning Guidelines - ERPG-1/ERPG-2/ERPG-3: 1 ppm/10 ppm/25 ppm
PEL-TWA mg/m3: NA	REL-TWA mg/m3: NA	
PEL-STEL ppm: 2	REL-STEL ppm: NA	
PEL-STEL mg/m3: NA	REL-STEL mg/m3: NA	
PEL-C ppm: NA	REL-C ppm: 0.1	
PEL-C mg/m3: NA	REL-C mg/m3: NA	**Carcinogen Classifications: IARC-2A, NIOSH-Ca, NTP-R, OSHA-Ca, TLV-A2**[4]
Skin Notation: No	Skin Notation: No	
Notes: SEE 29 CFR 1910.1048	Notes: **CARCINOGEN (Ca)**[4]**;** 15 MINUTE CEILING	
	IDLH ppm: 20	
	IDLH mg/m3: NA	
	IDLH Notes: Ca	

Although much of the information on carcinogenicity is pulled from sources used in Step I, additional information used to determine carcinogenicity may prove useful in completing a QCAT evaluation.

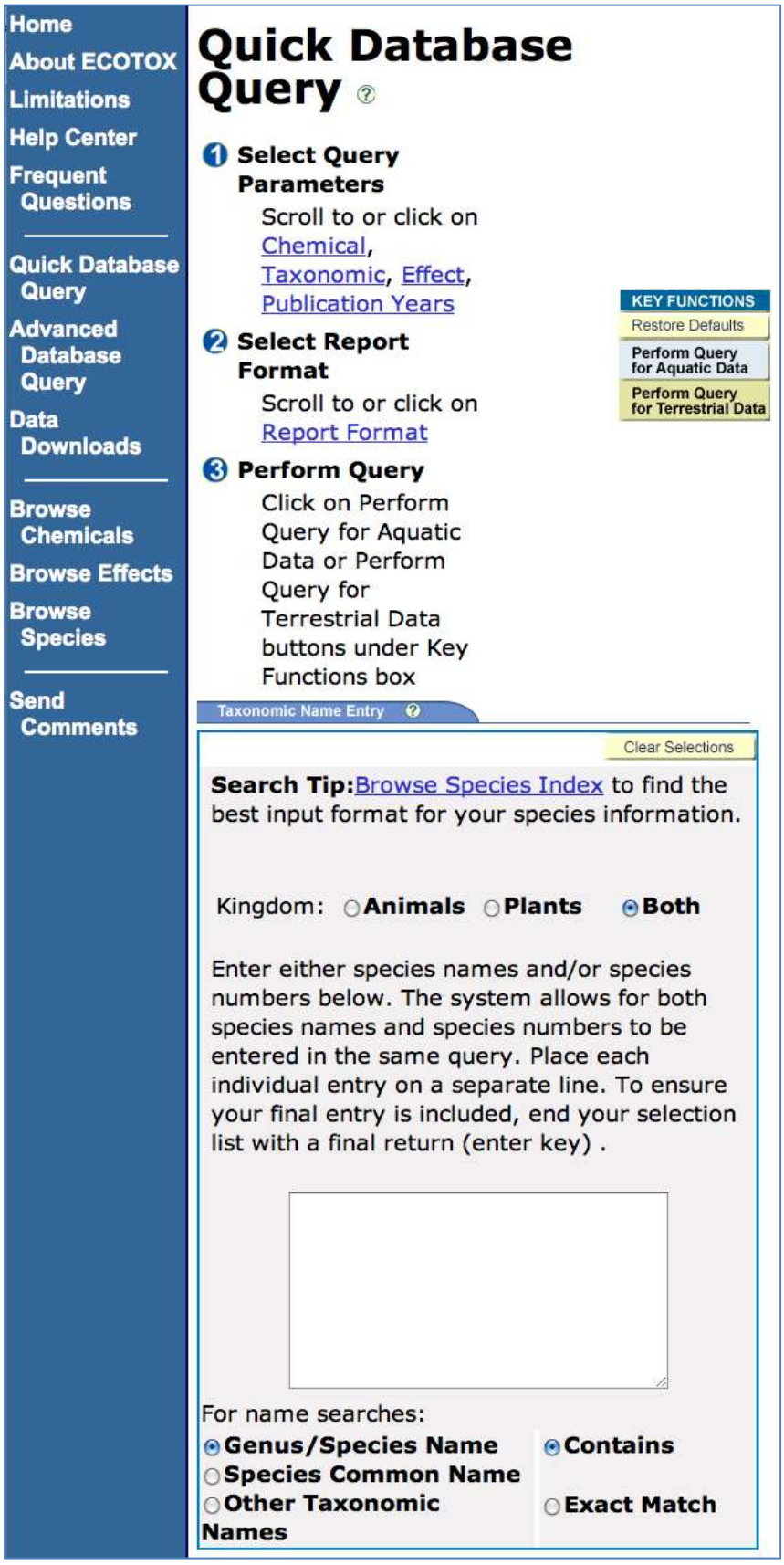
Ecological Toxicity (ECOTOX) Database:

ECOTOX is a major source of ecological toxicity information. However, unlike many of the previous sources, EPA does not conduct detailed technical review of all of the information included in ECOTOX. There will be more variability in the quality of data found within. To address this concern, a ‘weight of evidence’ approach will be used to identify values to be used in a QCAT evaluation. In addition, the exposure hierarchy described in the HSDB section above (Salmonids followed by fathead minnow, followed by any other fish species) will be used during data evaluation.

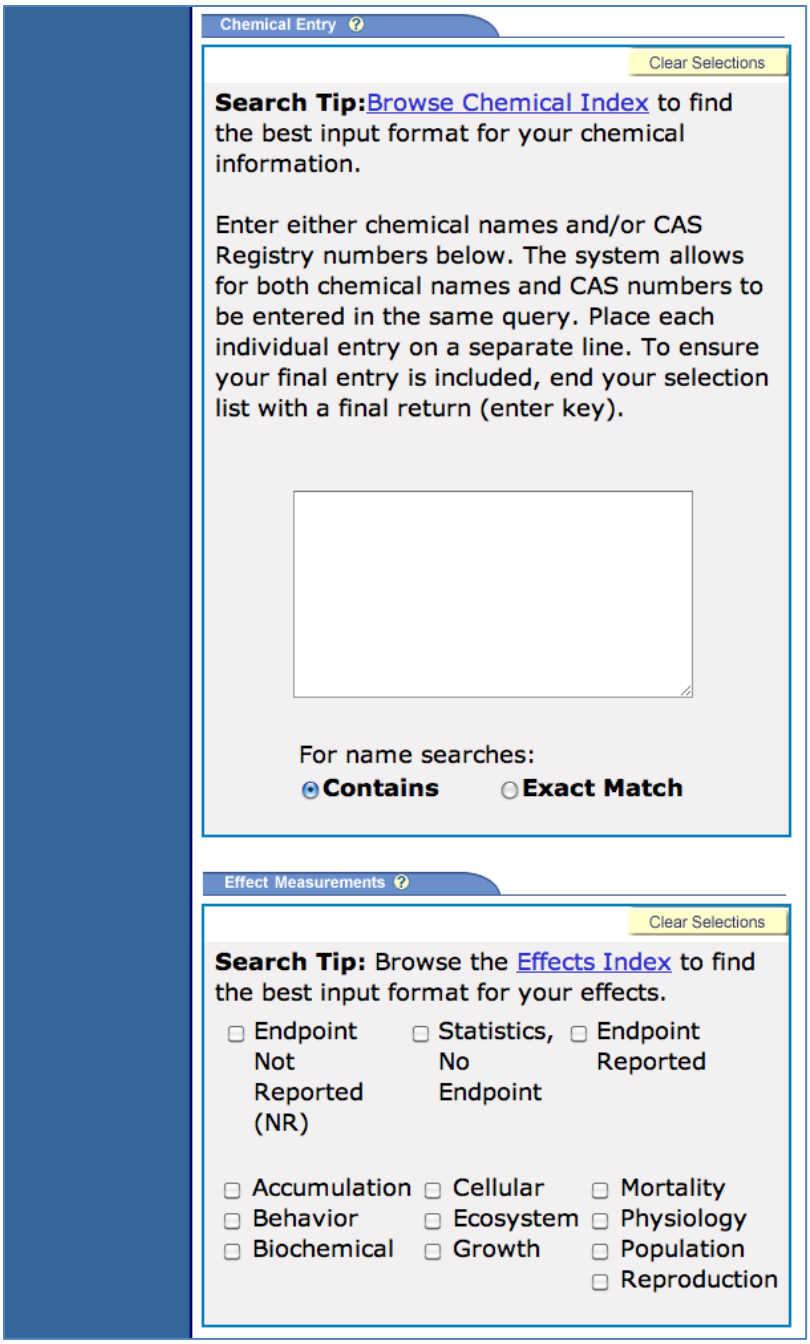
The ECOTOX opening page appears as follows:



The easiest way to request information from the database is to select the 'Quick Database Query' Option' which, once selected, appears as:

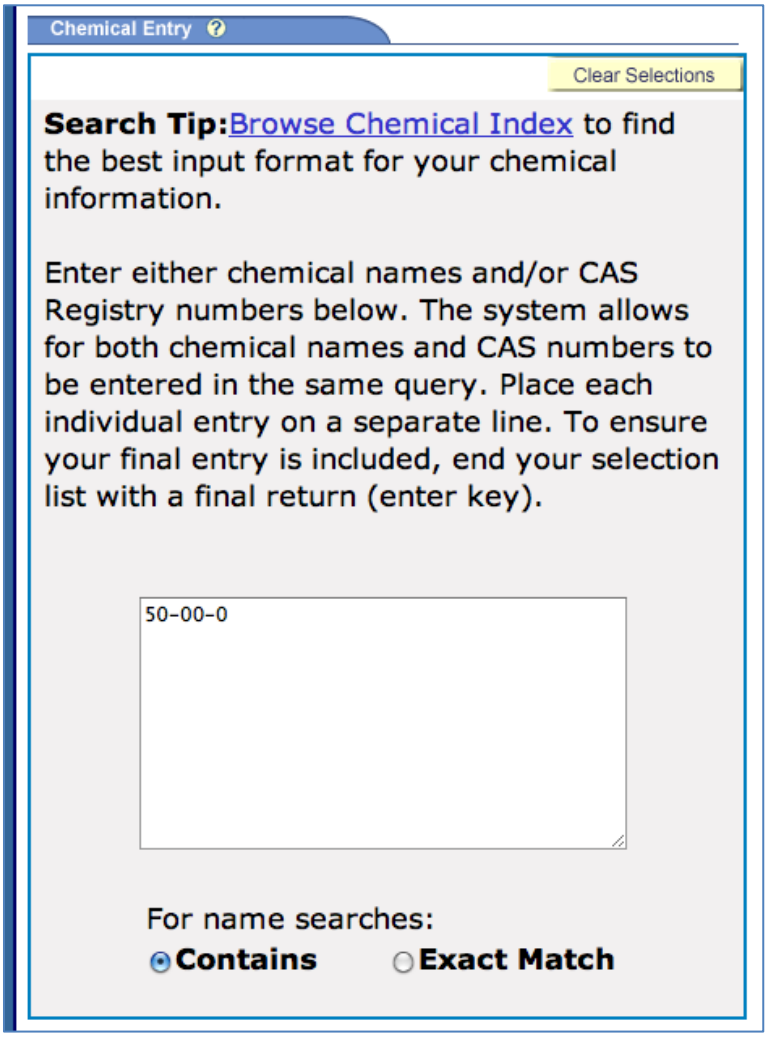


Screen capture continued on next page.



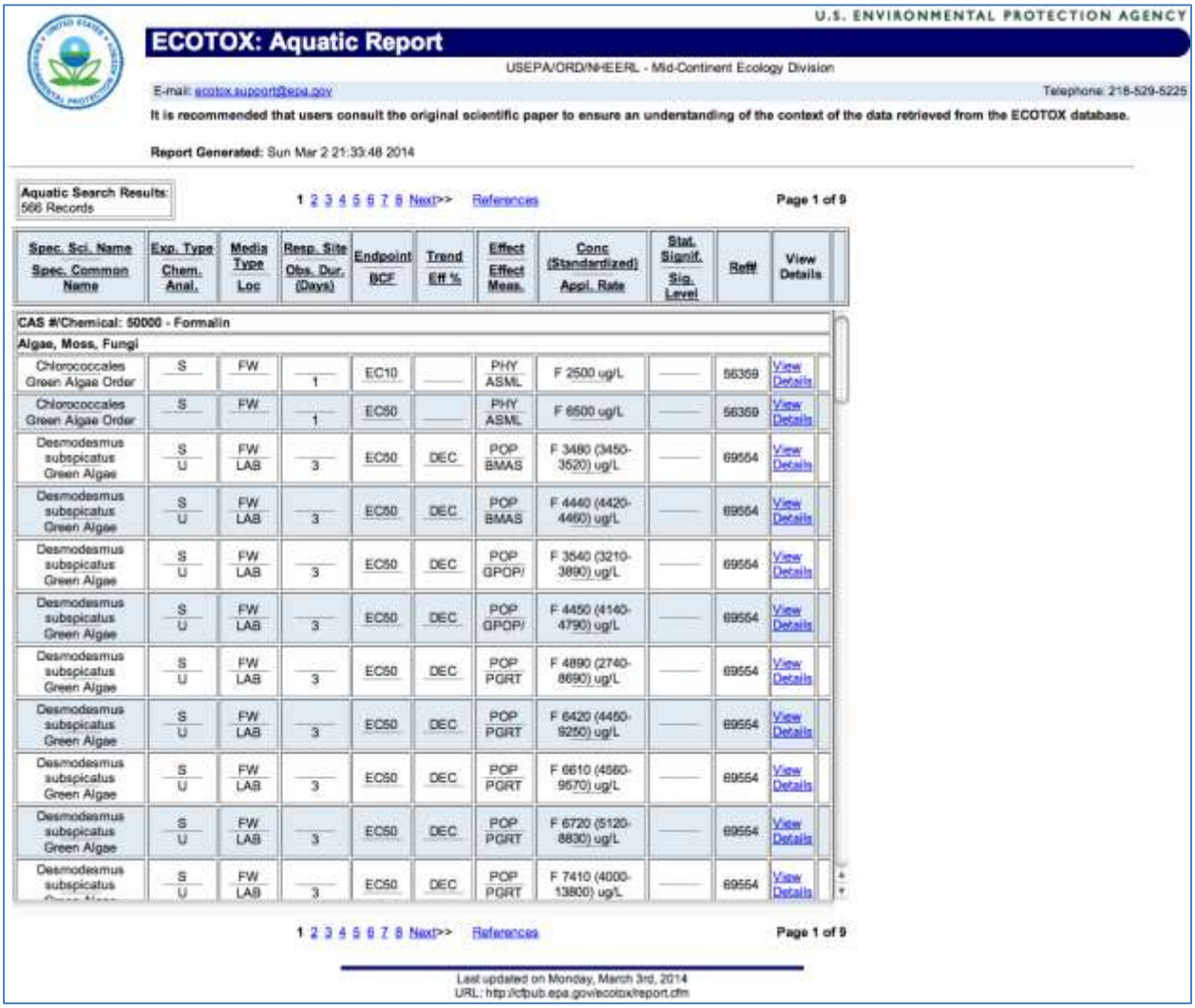
The screen captures above represent part of the information on the page. As can be seen, there are numerous ways to request data from ECOTOX. For most chemicals, there is limited information and the simplest method will work. In this instance, you enter the CAS number in the box labeled ‘Chemical Entry.’ No other changes are needed.

Using formaldehyde as an example, the entry would look like this:



Once the CAS number is entered into this box, the assessor clicks on the 'Perform Query for Aquatic Data.' A separate window will open that lists all of the information available in ECOTOX.

For example:



U.S. ENVIRONMENTAL PROTECTION AGENCY

ECOTOX: Aquatic Report

USEPA/ORD/NHEERL - Mid-Continent Ecology Division

E-mail: ecotox.support@epa.gov Telephone: 218-529-5225

It is recommended that users consult the original scientific paper to ensure an understanding of the context of the data retrieved from the ECOTOX database.

Report Generated: Sun Mar 2 21:33:48 2014

Aquatic Search Results: 566 Records

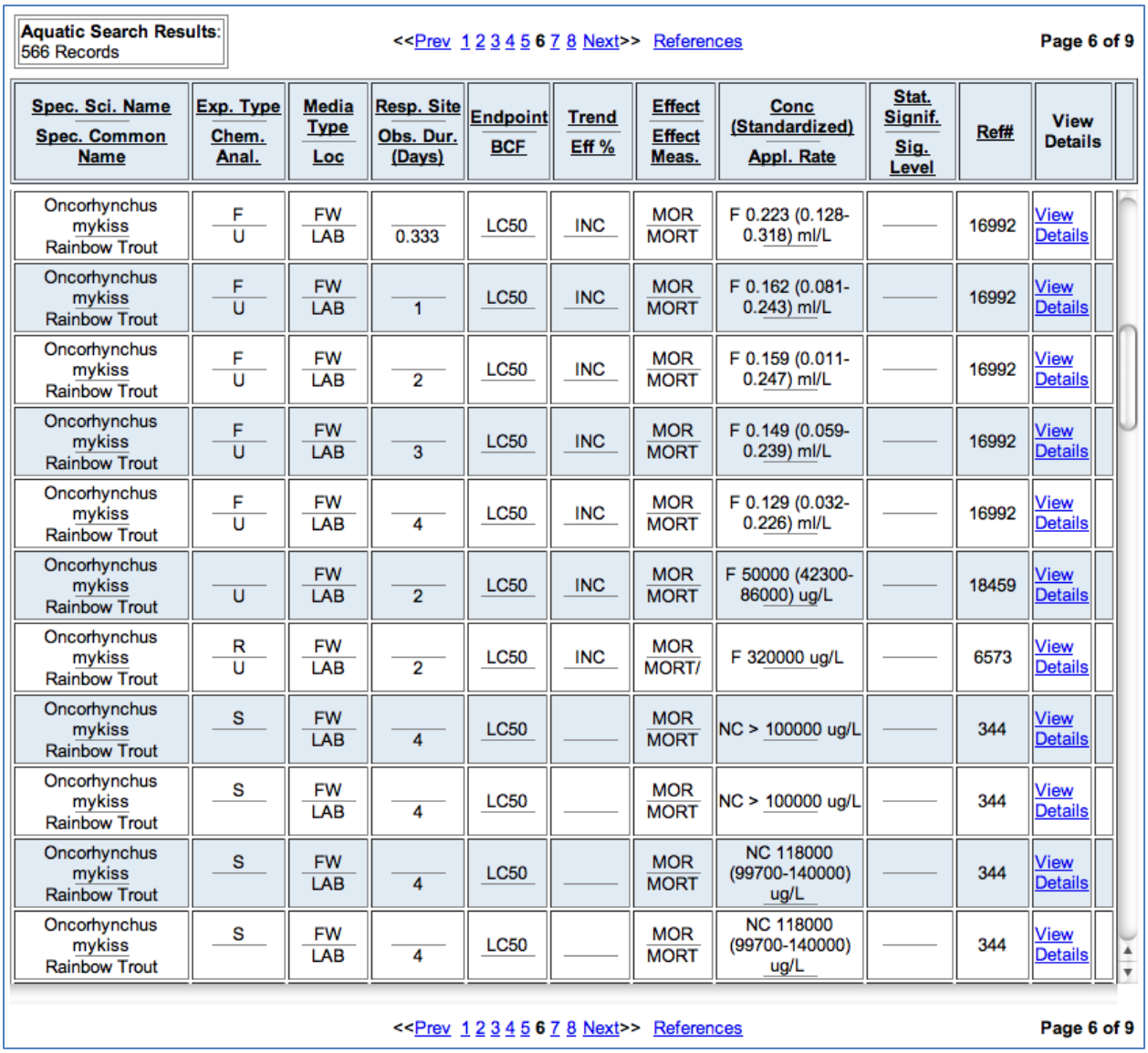
1 2 3 4 5 6 7 8 Next>> References Page 1 of 9

Spec. Sci. Name / Spec. Common Name	Exp. Type / Chem. Anal.	Media Type / Loc	Resp. Site / Obs. Dur. (Days)	Endpoint / BCF	Trend / Eff %	Effect / Effect Meas.	Conc (Standardized) / Appl. Rate	Stat. Signif. / Sig. Level	Ref#	View Details
CAS #/Chemical: 50000 - Formalin										
Algae, Moss, Fungi										
Chlorococcales Green Algae Order	S	FW	1	EC10		PHY ASML	F 2500 ug/L		56359	View Details
Chlorococcales Green Algae Order	S	FW	1	EC50		PHY ASML	F 6500 ug/L		56359	View Details
Desmodesmus subspicatus Green Algae	S U	FW LAB	3	EC50	DEC	POP BMAS	F 3480 (3450-3520) ug/L		69554	View Details
Desmodesmus subspicatus Green Algae	S U	FW LAB	3	EC50	DEC	POP BMAS	F 4440 (4420-4460) ug/L		69554	View Details
Desmodesmus subspicatus Green Algae	S U	FW LAB	3	EC50	DEC	POP GPOP/	F 3540 (3210-3890) ug/L		69554	View Details
Desmodesmus subspicatus Green Algae	S U	FW LAB	3	EC50	DEC	POP GPOP/	F 4450 (4140-4790) ug/L		69554	View Details
Desmodesmus subspicatus Green Algae	S U	FW LAB	3	EC50	DEC	POP PGRT	F 4890 (2740-8690) ug/L		69554	View Details
Desmodesmus subspicatus Green Algae	S U	FW LAB	3	EC50	DEC	POP PGRT	F 6420 (4450-9250) ug/L		69554	View Details
Desmodesmus subspicatus Green Algae	S U	FW LAB	3	EC50	DEC	POP PGRT	F 6610 (4560-9570) ug/L		69554	View Details
Desmodesmus subspicatus Green Algae	S U	FW LAB	3	EC50	DEC	POP PGRT	F 6720 (5120-8830) ug/L		69554	View Details
Desmodesmus subspicatus	S U	FW LAB	3	EC50	DEC	POP PGRT	F 7410 (4000-13800) ug/L		69554	View Details

1 2 3 4 5 6 7 8 Next>> References Page 1 of 9

Last updated on Monday, March 3rd, 2014
URL: http://cfpub.epa.gov/ecotox/report.cfm

Formaldehyde contains numerous acute aquatic toxicity (LC_{50}) entries for Rainbow Trout. An excerpt of this data follows on the next page.



Aquatic Search Results: 566 Records

<<Prev 1 2 3 4 5 6 7 8 Next>> References — Page 6 of 9

Spec. Sci. Name / Spec. Common Name	Exp. Type / Chem. Anal.	Media Type / Loc	Resp. Site / Obs. Dur. (Days)	Endpoint / BCF	Trend / Eff %	Effect / Effect Meas.	Conc (Standardized) / Appl. Rate	Stat. Signif. / Sig. Level	Ref#	View Details
Oncorhynchus mykiss Rainbow Trout	F U	FW LAB	0.333	LC50	INC	MOR MORT	F 0.223 (0.128-0.318) ml/L		16992	View Details
Oncorhynchus mykiss Rainbow Trout	F U	FW LAB	1	LC50	INC	MOR MORT	F 0.162 (0.081-0.243) ml/L		16992	View Details
Oncorhynchus mykiss Rainbow Trout	F U	FW LAB	2	LC50	INC	MOR MORT	F 0.159 (0.011-0.247) ml/L		16992	View Details
Oncorhynchus mykiss Rainbow Trout	F U	FW LAB	3	LC50	INC	MOR MORT	F 0.149 (0.059-0.239) ml/L		16992	View Details
Oncorhynchus mykiss Rainbow Trout	F U	FW LAB	4	LC50	INC	MOR MORT	F 0.129 (0.032-0.226) ml/L		16992	View Details
Oncorhynchus mykiss Rainbow Trout	U	FW LAB	2	LC50	INC	MOR MORT	F 50000 (42300-86000) ug/L		18459	View Details
Oncorhynchus mykiss Rainbow Trout	R U	FW LAB	2	LC50	INC	MOR MORT/	F 320000 ug/L		6573	View Details
Oncorhynchus mykiss Rainbow Trout	S	FW LAB	4	LC50		MOR MORT	NC > 100000 ug/L		344	View Details
Oncorhynchus mykiss Rainbow Trout	S	FW LAB	4	LC50		MOR MORT	NC > 100000 ug/L		344	View Details
Oncorhynchus mykiss Rainbow Trout	S	FW LAB	4	LC50		MOR MORT	NC 118000 (99700-140000) ug/L		344	View Details
Oncorhynchus mykiss Rainbow Trout	S	FW LAB	4	LC50		MOR MORT	NC 118000 (99700-140000) ug/L		344	View Details

<<Prev 1 2 3 4 5 6 7 8 Next>> References — Page 6 of 9

Many of the LC_{50} results can be discarded because the test lasted less than 24 hours (0.333 days). The remaining tests which lasted anywhere from 1 to 4 days provided results ranging from 1,410 to 320,000 µg/L. However, the low values were found in a limited number of studies and a majority of the results were in the 100,000 to 200,000 µg/L range. Therefore a value of 150,000 micrograms per liter (equivalent to 150 mg/L) would be selected for the QCAT as being most representative of the data in ECOTOX.

ECOTOX also contains information on a chemical's bioaccumulation factor. As with other information, the user must determine which BCF values to use. A 'weight of evidence' approach as shown in other examples in this document might be a preferred method. However, if bioaccumulation information cannot be found in the other sources or confirmatory values are needed, ECOTOX may prove a valuable source to determine whether or not a chemical bioaccumulates.

ISSCAN Chemical Carcinogens: Structures and Experimental Data:

ISSCAN is an Italian database which contains information on carcinogen and mutagen potential based upon technical review of scientific studies and computer modeling input using Quality Structure Activity Relationship ((Q)SAR) processes. The information is provided in an Excel spreadsheet and information on both the carcinogenic and mutagenic potential is provided.

The data are presented in a range from 1 to 3 where:

- 3 = carcinogenic or mutagenic
- 2 = undetermined or equivocal
- 1 = non-carcinogenic or non-mutagenic

Some chemicals were not evaluated particularly for mutagenicity due to a lack of data and are identified as 'nd' for 'no data.'

For example, the ISSCAN provides the following information (additional detail excluded for the purposes of a QCAT review)

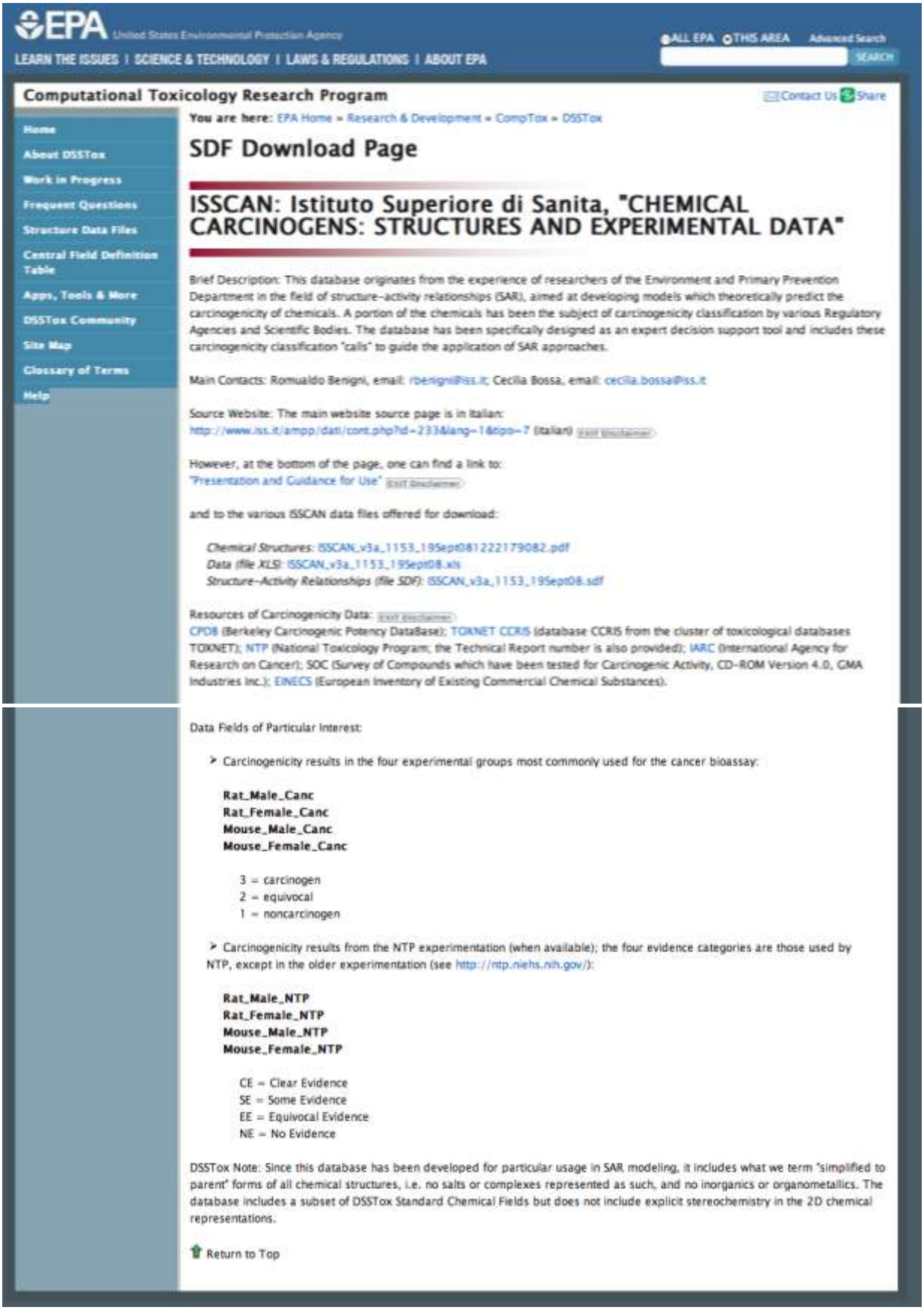
ChemName	CAS	Canc	SAL[17]
Vinyl chloride	75-01-4	3	3

Therefore for the purposes of the QCAT, vinyl chloride would be identified as a known carcinogen and known mutagen.

Access to the ISSCAN data is via an EPA website.

[17] SAL = Mutagenicity in *Salmonella typhimurium* (Ames Test)

The EPA page appears as:



EPA United States Environmental Protection Agency

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You are here: EPA Home » Research & Development » CompTox » DSSTox

SDF Download Page

ISSCAN: Istituto Superiore di Sanita, "CHEMICAL CARCINOGENS: STRUCTURES AND EXPERIMENTAL DATA"

Brief Description: This database originates from the experience of researchers of the Environment and Primary Prevention Department in the field of structure-activity relationships (SAR), aimed at developing models which theoretically predict the carcinogenicity of chemicals. A portion of the chemicals has been the subject of carcinogenicity classification by various Regulatory Agencies and Scientific Bodies. The database has been specifically designed as an expert decision support tool and includes these carcinogenicity classification "calls" to guide the application of SAR approaches.

Main Contacts: Romualdo Benigni, email: rbenigni@iss.it; Cecilia Bossa, email: cecilia.bossa@iss.it

Source Website: The main website source page is in Italian:
http://www.iss.it/ampp/dati/cont.php?id=233&lang=1&tipo=7 (Italian) Exit Disclaimer

However, at the bottom of the page, one can find a link to:
"Presentation and Guidance for Use" Exit Disclaimer

and to the various ISSCAN data files offered for download:

Chemical Structures: ISSCAN_v3a_1153_19Sept081222179082.pdf
Data (file XLS): ISSCAN_v3a_1153_19Sept08.xls
Structure--Activity Relationships (file SDF): ISSCAN_v3a_1153_19Sept08.sdf

Resources of Carcinogenicity Data: Exit Disclaimer
CPDB (Berkeley Carcinogenic Potency DataBase); TOXNET CCRIS (database CCRIS from the cluster of toxicological databases TOXNET); NTP (National Toxicology Program; the Technical Report number is also provided); IARC (International Agency for Research on Cancer); SOC (Survey of Compounds which have been tested for Carcinogenic Activity, CD-ROM Version 4.0, GMA Industries Inc.); EINECS (European Inventory of Existing Commercial Chemical Substances).

Data Fields of Particular Interest:

- Carcinogenicity results in the four experimental groups most commonly used for the cancer bioassay:

Rat_Male_Canc
Rat_Female_Canc
Mouse_Male_Canc
Mouse_Female_Canc

3 = carcinogen
2 = equivocal
1 = noncarcinogen

- Carcinogenicity results from the NTP experimentation (when available); the four evidence categories are those used by NTP, except in the older experimentation (see http://ntp.niehs.nih.gov/):

Rat_Male_NTP
Rat_Female_NTP
Mouse_Male_NTP
Mouse_Female_NTP

CE = Clear Evidence
SE = Some Evidence
EE = Equivocal Evidence
NE = No Evidence

DSSTox Note: Since this database has been developed for particular usage in SAR modeling, it includes what we term "simplified to parent" forms of all chemical structures, i.e. no salts or complexes represented as such, and no inorganics or organometallics. The database includes a subset of DSSTox Standard Chemical Fields but does not include explicit stereochemistry in the 2D chemical representations.

Return to Top

The ISSCAN data can be downloaded from the link in the middle of the page (*Data (file XLS*): ISSCAN_v3a_1153_19Sept08.xls). The QCAT user can search the Excel spreadsheet by CAS number for any available data.

Danish Ministry of the Environment's Environmental Protection Agency (Danish EPA) (Q)SAR Assessment of Chemical Properties of Substances

The Danish EPA has created a database that contains predictions on the potential toxicity of approximately 166,000 chemicals. The database predicts toxicity for the following criteria of importance to the QCAT:

- Mutagenicity
- Carcinogenicity
- Reproductive toxicity
- Aquatic environment
- Acute human (oral) toxicity

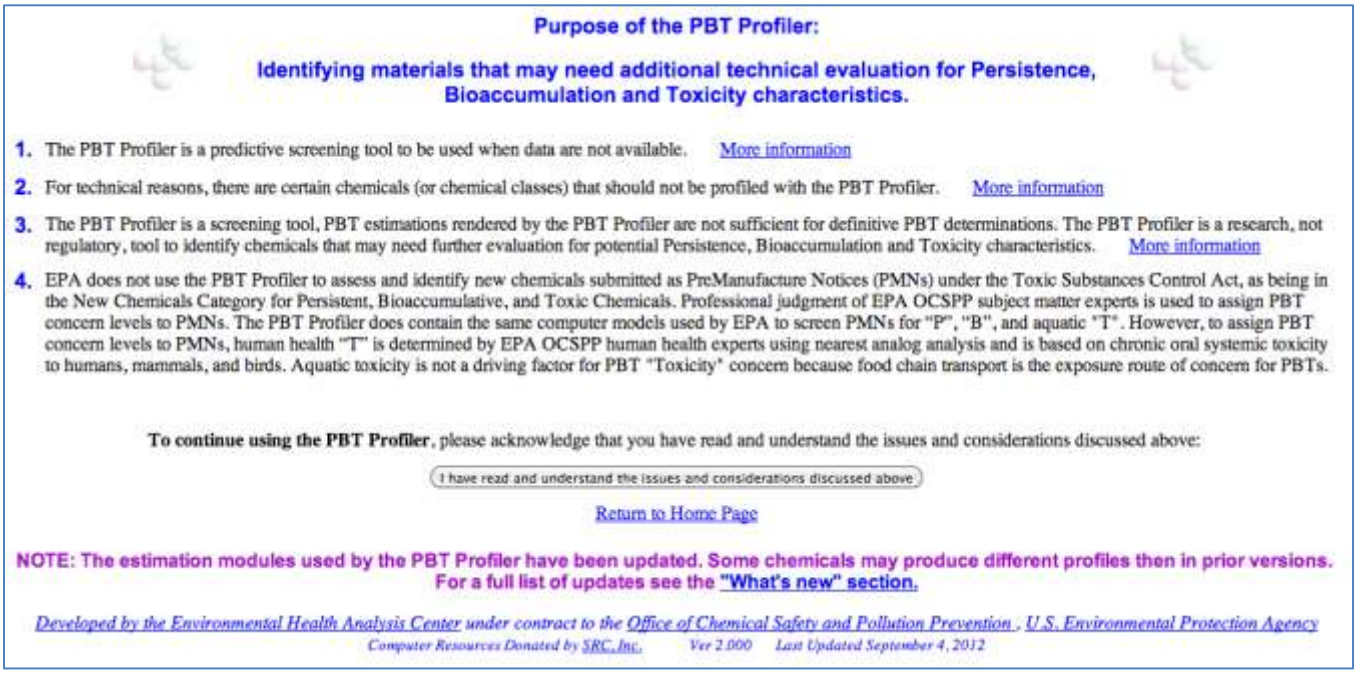
For the purposes of the QCAT, the full (Q)SAR database will not be used but a subset of more than 30,000 substances for which GHS classifications have been estimated. These GHS results are directly comparable to the GHS criteria included in the Appendix 8 of QCAT.

PBT Profiler:

The U.S. EPA has developed a system for assessing chemicals for persistence and bioaccumulation when experimental data are absent. This system, the PBT Profiler, is used as screening tool to estimate persistence and bioaccumulation criteria and should only be used when other sources of information are not available.

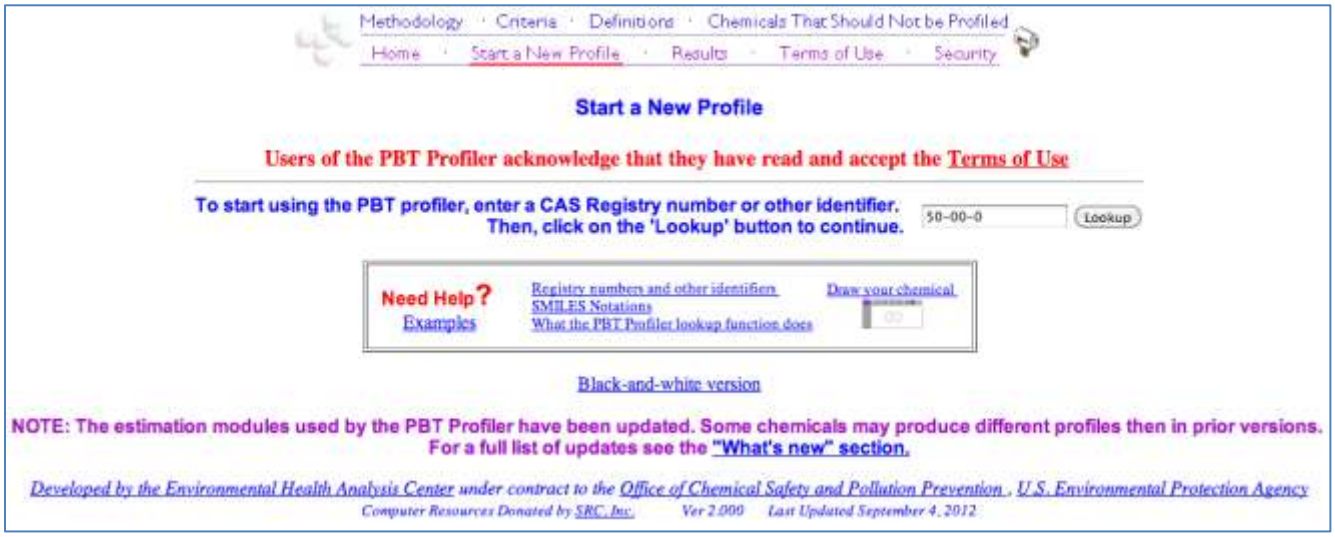
The initial screen of the PBT Profiler appears as:

Clicking on ‘Start the PBT Profiler’ takes you to the following page:

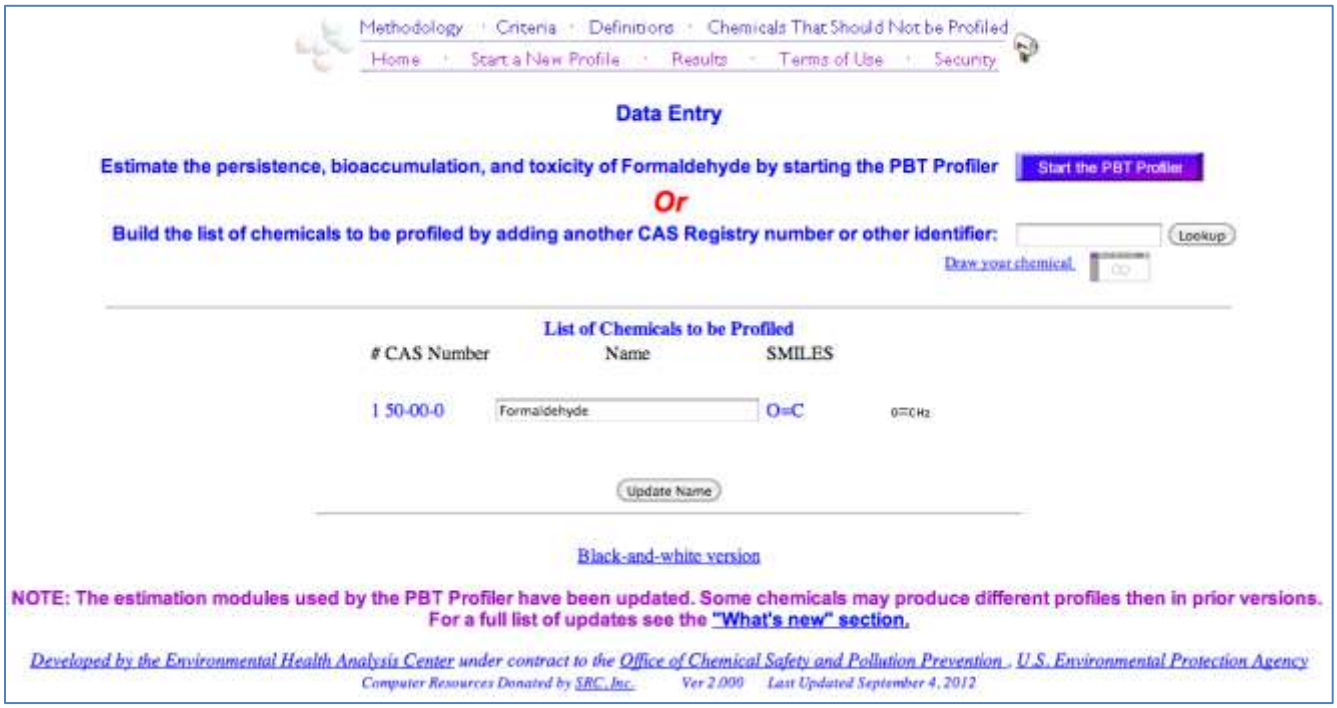


Agreeing to the issues and considerations takes you to the following page:

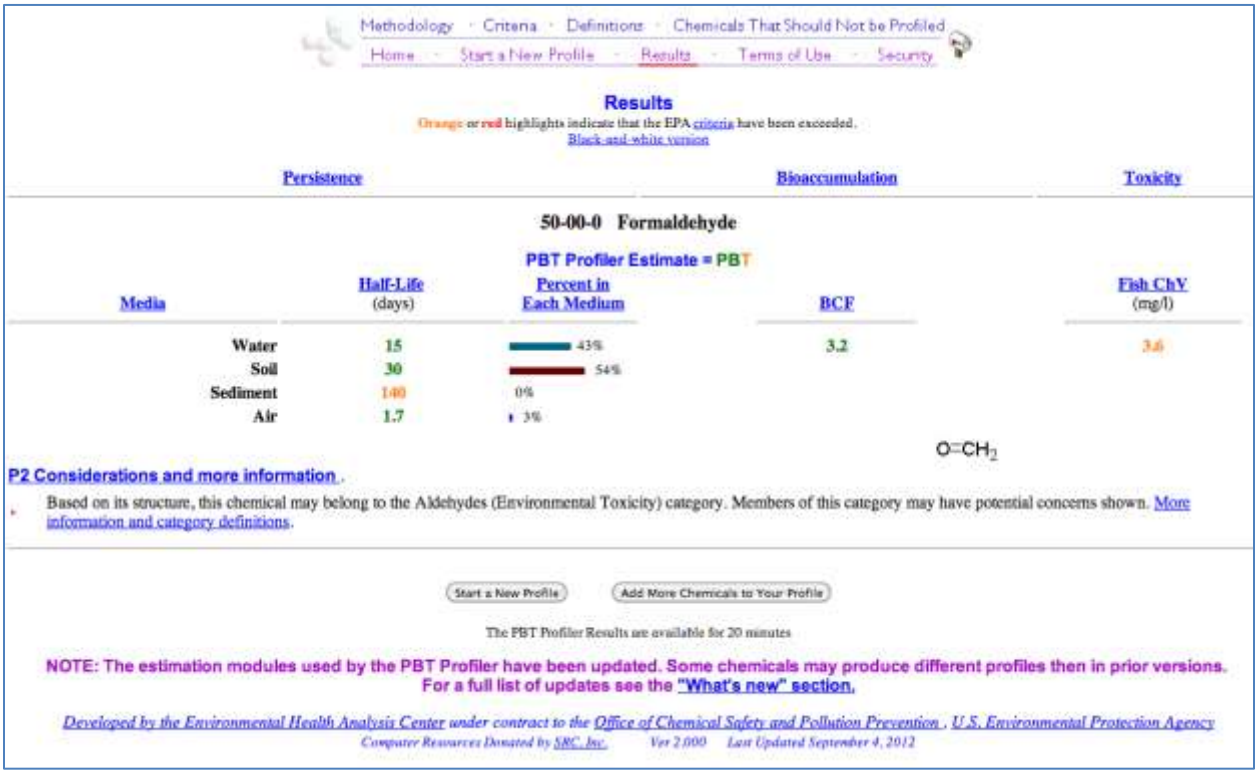
You may now actually start the PBT Profiler.



Using formaldehyde as an example, enter its CAS number into the box and click on ‘Lookup’. The following page appears:



Search for data on multiple chemicals by entering information on a second chemical and pressing 'Lookup' or look at the report on a single chemical by selecting the 'Start the PBT Profiler' option, which produces the following:



Various media including water, soil, sediment, and air display persistence results. When considering whether a chemical is persistent, it would be appropriate to consider what media is mostly likely to be the major factor for the chemical under evaluation. In the case of formaldehyde, the half-life values for water and soil are most important as these two media account for 97% of the media in which it is distributed. Sediment and air comprise only 3% and their half-life values are less likely to impact whether or not formaldehyde is persistent.

In addition to persistence, the PBT Profiler also includes information on bioaccumulation and toxicity. The bioaccumulation tendency is displayed as a projected bioaccumulation factor (BCF). This information may prove useful in filling in any gaps that remain for these criteria. The toxicity values, however, cannot be translated into a level of concern using the DfE criteria and therefore are unlikely to help in the chemical assessment.

1. EU Risk Assessments (RA):

The European Commission maintained a list of chemicals that have undergone or are undergoing the risk assessment process. Many of these reports can be found in the Classification and Labeling Database. The assessor may wish to conduct an internet search to see if an EU Risk Assessment was completed for the chemical of interest. If a risk assessment has been completed for a chemical of interest, additional data reviewed during the process by experts in the various toxicity criteria and the conclusions reached may prove useful in filling any remaining data gaps. The EU uses a standardized

format for all risk assessments which makes access to information easier. The following is a page from the EU RA for trichloroethylene which demonstrates the overall structure:

The RAR includes an evaluation of human health and environmental toxicity including many of the QCAT criteria including:

- Biodegradation
- Bioaccumulation
- Mutagenicity
- Carcinogenicity

- Aquatic toxicity
- Acute mammalian toxicity
- Reproductive toxicity

At the end of each toxicity criteria, the RAR typically either selects a value culled from the scientific data or reaches a conclusion, which may be useful to the QCAT process.

Chapter 4 deals with mammalian toxicity and includes a number of hazard criteria of interest. At the end of each section, the RAR summarizes what can be learned from the evaluation. Information in these summary sections may be useful when assigning a level of concern for specific hazard endpoints.

For example, Section 4.1.2.8 deals with carcinogenicity and subsection 4.1.2.8.3 '*Summary of carcinogenicity studies'* summarizes carcinogenicity conclusions that can be obtained from the previous discussions. Continuing with trichloroethylene as an example, the following information was copied from the end of the RAR section on carcinogenicity (page 231):

in support of category 1, underlined the evidence for kidney tumours in humans and the consistency with the *S*-(1,2-dichlorovinyl)-L-cysteine (DCVC) metabolic pathway and the observation of a different spectrum of somatic mutations in kidney tumours of trichloroethylene-exposed compared to unexposed patients.

A clear majority of the Specialised Experts recommended that classification of trichloroethylene as a category 2 carcinogen is warranted, based on evidence in one animal species, namely tumours in the rat kidney, supported by epidemiological data showing an association between exposure and kidney tumours and non-Hodgkin's lymphoma in humans. Some Specialised Experts stated that genotoxicity and metabolic/biochemical findings added to their concern. One expert maintained that category 1 was appropriate, one preferred category 3 but accepted the majority view.

The summary information like '*A clear majority of the Specialised Experts recommended that classification of trichloroethylene as a category 2 carcinogen is warranted…'* can be used by the assessor to identify a level of concern.

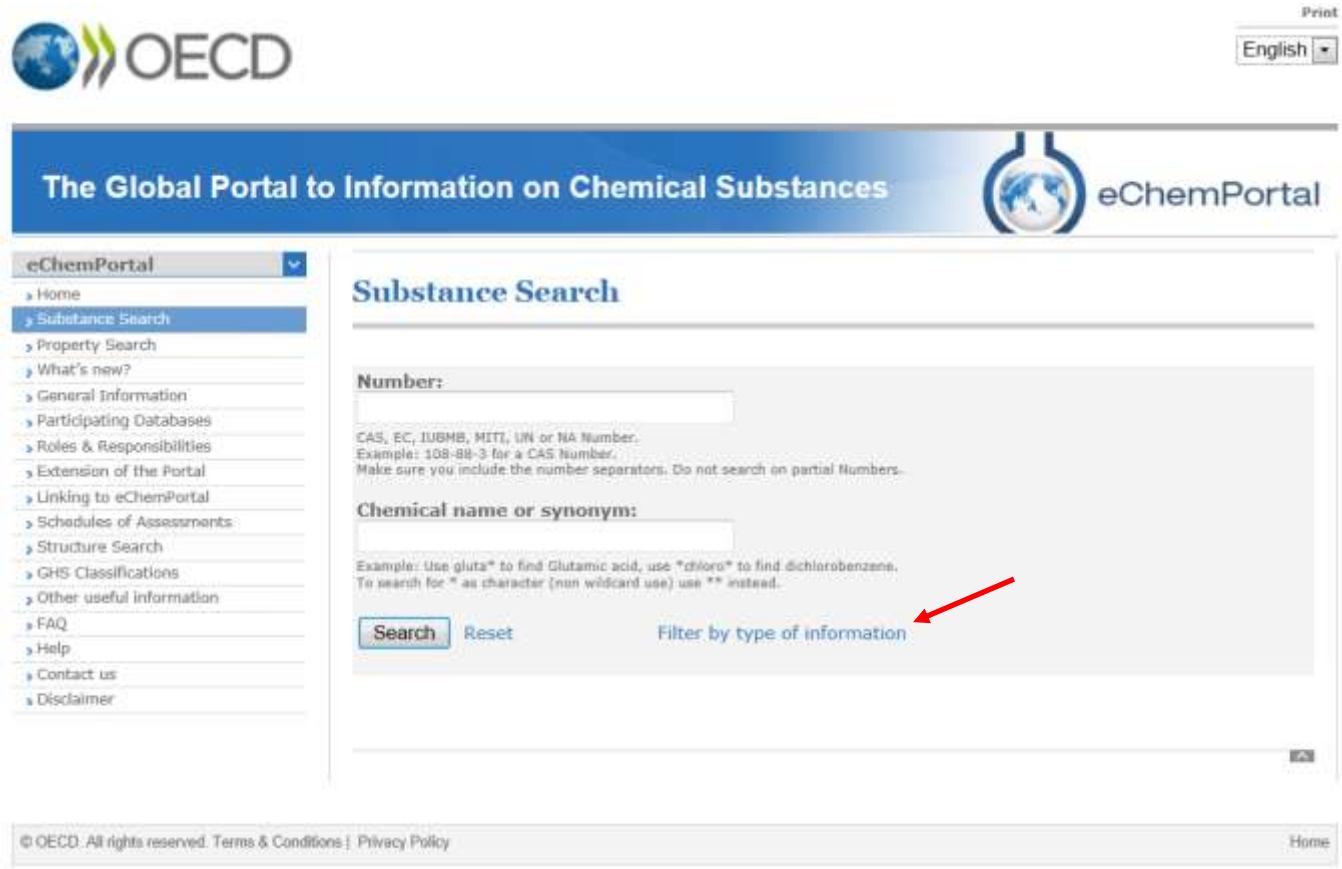
Unlike the sources in Step I, more searching is needed to determine the conclusions reached by the experts and reported in the RAR. In some instances, no distinct conclusion was reached. It is not expected that any of the details in the RAR would be used for the purposes of the QCAT if no conclusion was reached. Where such information is found, however, it may be useful in filling any data gaps which exist after a review using Step I sources. The QCAT review is limited to this level of review.

2. IUCLID Datasheets:

IUCLID datasheets give the user access to data submitted to the EU on specific chemicals. This information may be available from several sources. The assessor may download a copy of the IUCLID database which includes information submitted on specific chemicals. In addition, IUCLID datasheets may be provided, if available, in the European Union's Classification and Labeling database. Assessors may also access IUCLID datasheets through the OECD's Global Portal to Information on Chemical Substances, also known as eChemPortal.

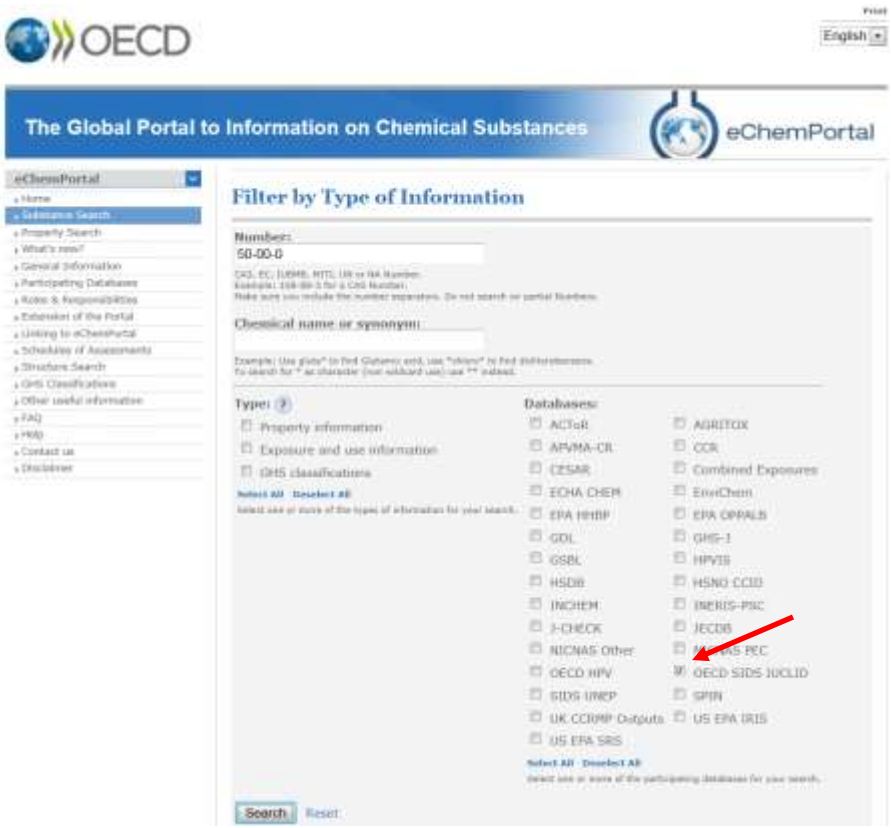
eChemPortal provides access to many sources of chemical data and is a valuable tool used by assessors conducting a complete hazard assessment like the GreenScreen. Assessors conducting a QCAT should be careful to limit their review to Step II sources, one of which is the EUCLID datasheets.

The following shows the initial eChemPortal page:

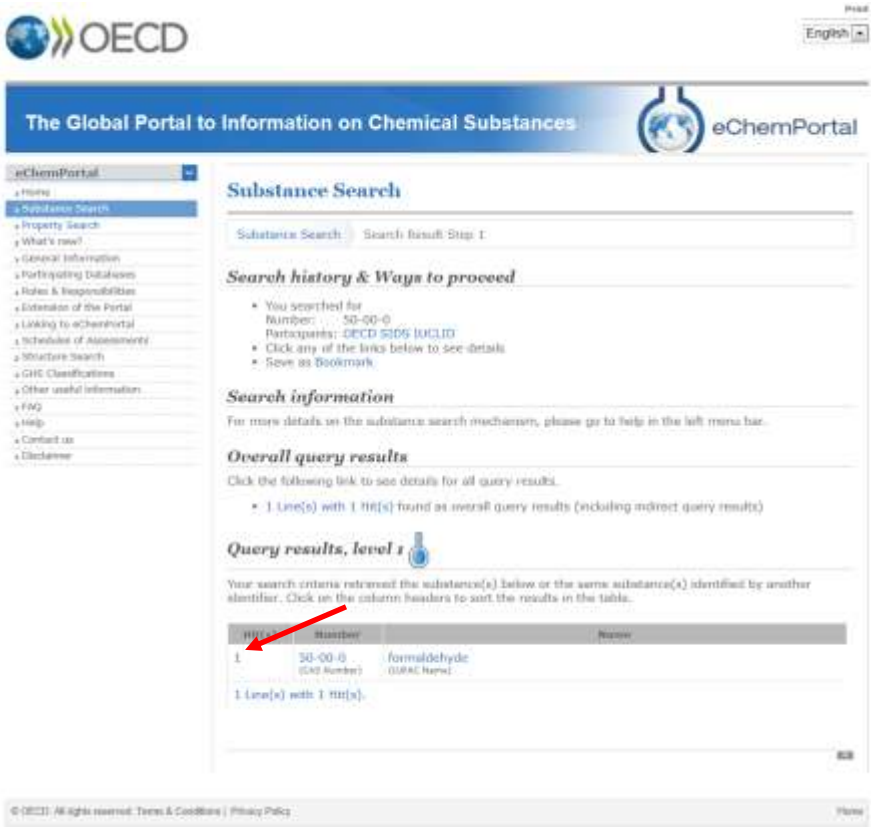


Extreme care should be taken in using the data reported in these datasheets, however, as data presented may not have undergone any peer review. As companies who have a vested interest in the chemical submitted the data, caution should be used in interpreting these results.

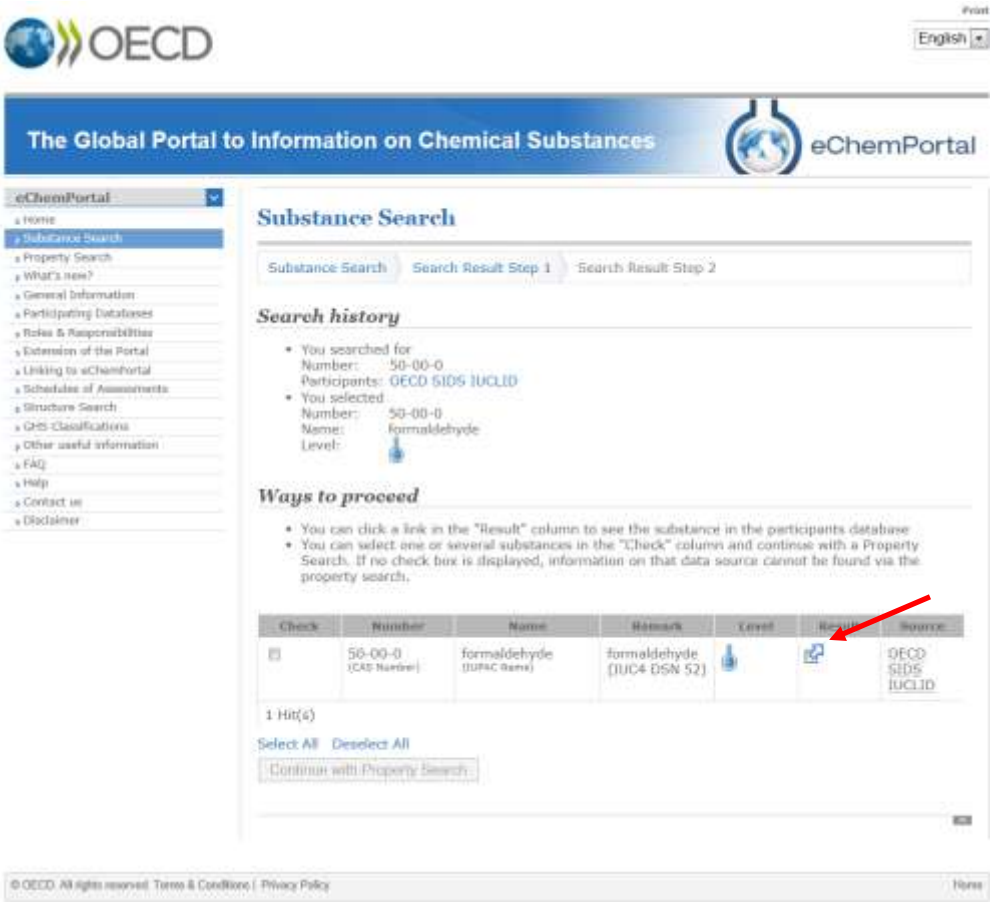
eChemPortal allows the assessor limit data sources. Clicking on the 'Filter by type of information' (red arrow above', the following appears:



Making sure only the 'OECD SIDS IUCLID' button (red arrow) is the only one selected restricts the search solely to IUCLID information. The CAS number is entered in the 'Number' slot and 'Search' clicked. Using the CAS number for formaldehyde as an example, the following information appears:



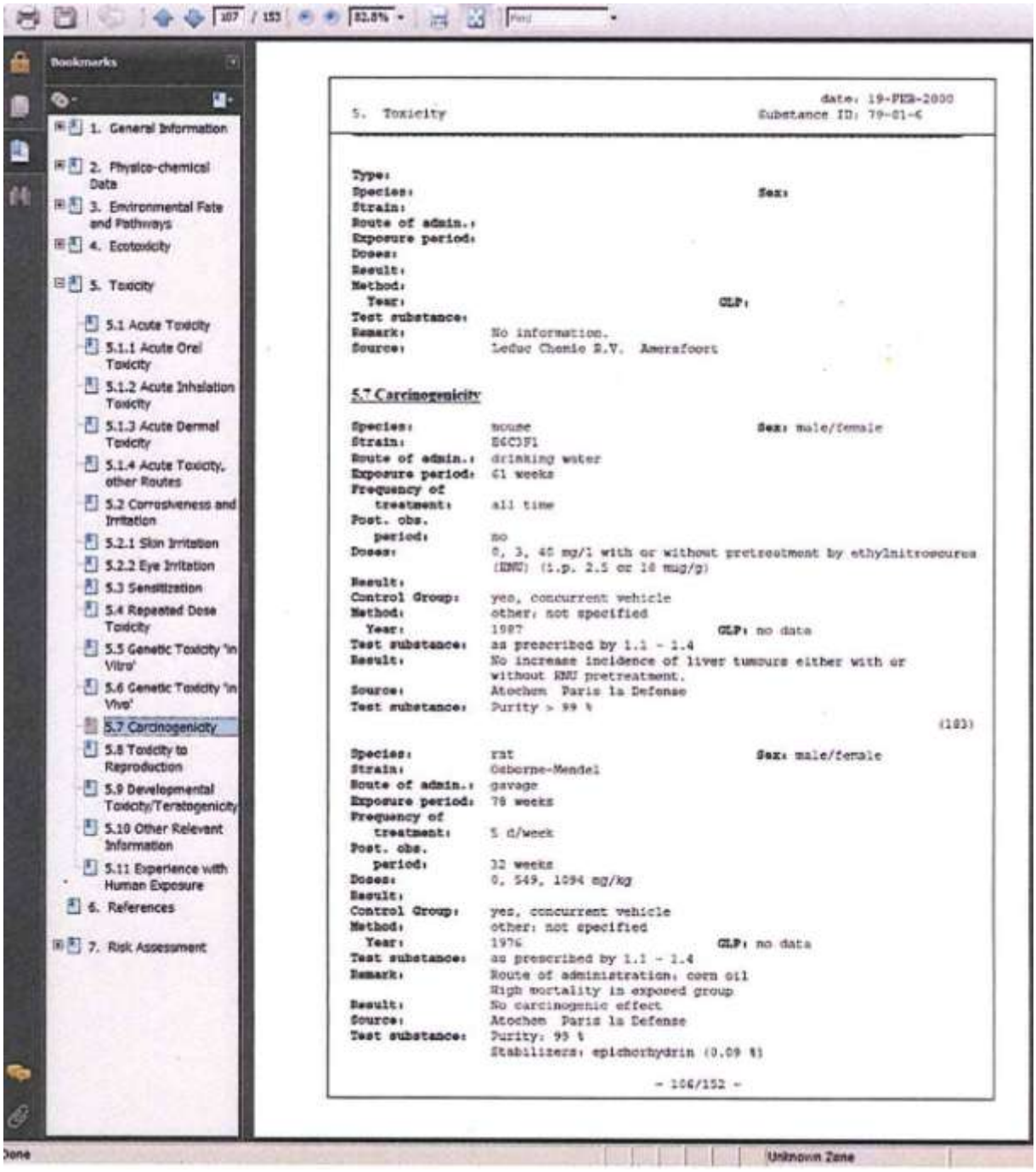
Clicking on the ‘1’ (red arrow) takes the assessor to the actual record:



Clicking on the icon in the ‘Result’ column takes the assessor directly to the IUCLID dataset.

If no other information is available, the IUCLID datasheet may be able to give the reviewer information, which will assist in the QCAT process. Information may be found in the dataset for all of the hazard criteria used by the QCAT except endocrine activity.

The IUCLID datasets have a standardized format which increases the assessor’s ability to find important data. The following is the title page for the IUCLID dataset for trichloroethylene:

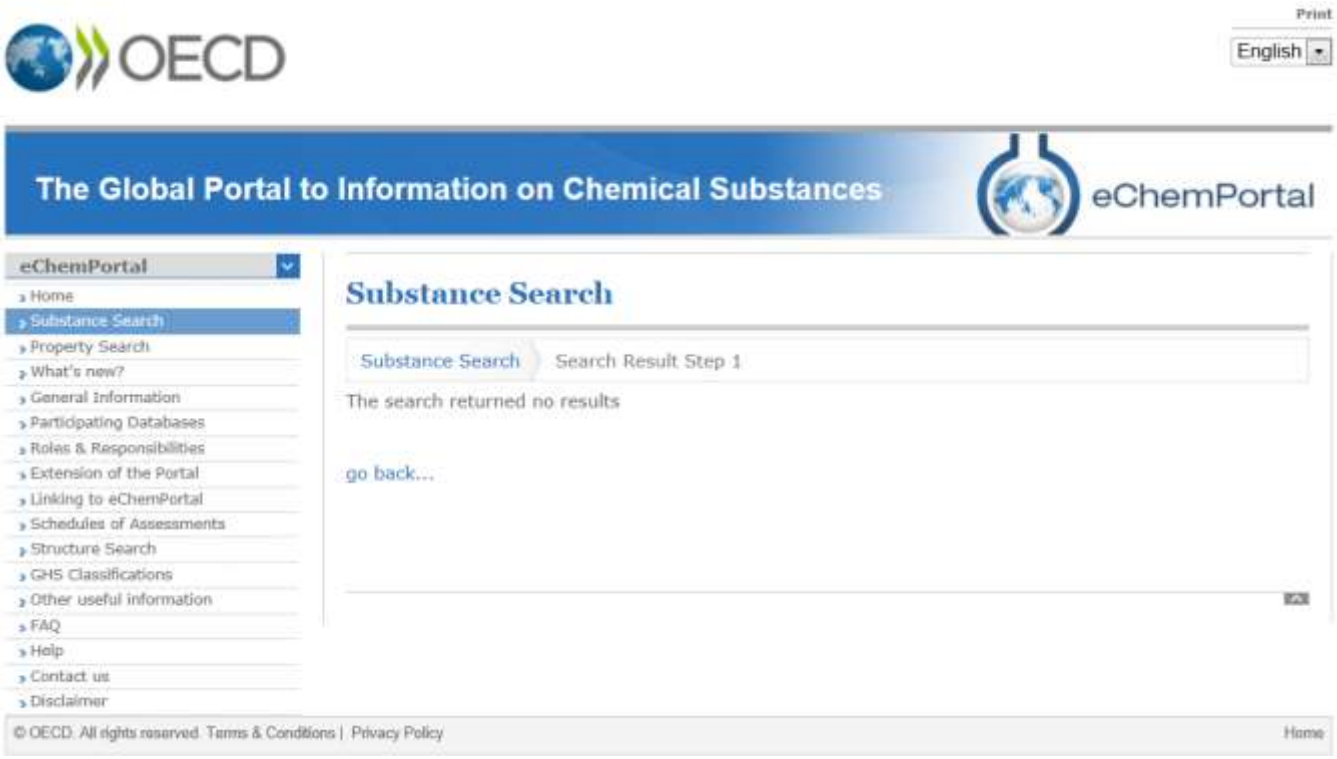


By clicking on the parameter of interest in the window on the left, information relevant to the specific hazard criteria appears in the window on the right. It is then possible to scroll through the results and determine whether the studies included indicate whether the toxicity criteria are of concern.

Evaluation of each specific test report in the dataset is outside the level of expertise expected for implementation of the QCAT. However, it may be possible using a 'weight of evidence' approach to indicate whether the toxicity criteria are a problem. For example, if the dataset included 12 studies, 10 of which were negative and two positive, the data would suggest that it is unlikely the toxicity criteria is a problem. It is this level of detail expected for evaluation of information in the IUCLID datasets.

As indicated previously, the datasets should be used with caution. In addition because the data has not undergone technical review, the datasets should be used **only when no other data are available or as a confirmation for data from other sources**.

Lastly, if the assessor follows this process but no IUCLID datasheet is available, the following window will appear:



Appendix 3: Example Hazard Comparison Table

Data found:

Chem-ical	CAS	Human - Group 1					Human - Group 2							Eco			Fate		Physical	
		C	M	R	D	E	AT	ST	N	SnS	SnR	IrS	IrE	AA	CA	Eo	P	B	Ex	F
1	1234-56-1	IRIS 1986 Cat. A	GHS Cat. 2	GHS Risk R62	Prop 65 on list	EU Cat. 1	Oral LD_{50} = 25mg/kg	X	X	X	X	X	X	Fish LC_{50} = 0.5mg/L	X	X	Soil $t_{1/2}$ = 2,000d	WA PBT on list	X	X
2	1234-56-2	IRIS 1986 Cat. E	Meets DfE low Screen	Oral LOAEL = 500 mg/kg	EU RA no sign	No Data	Oral LD_{50}= 3000 mg/kg	X	X	X	X	X	X	Oral LD_{50} = 3,000 mg/kg	X	X	Soil $t_{1/2}$ = 25 d	BCF = 560	X	X
3	1234-56-3	IARC Group 4	Risk Phrase R 47	No Data	Risk PhraseR62	No Data	DG	X	X	X	X	X	X	GHS Cat. 3	X	X	No Data	EU RA No B	X	X

Summary based upon existing data:

Chemical	CAS	Human - Group 1					Human - Group 2							Eco			Fate		Physical	
		C	M	R	D	E	AT	ST	N	SnS	SnR	IrS	IrE	AA	CA	Eo	P	B	Ex	F
1	1234-56-1	H	M	M	H	H	vH	X	X	X	X	X	X	H	X	X	vH	vH	X	X
2	1234-56-2	L	L	L	L	DG	L	X	X	X	X	X	X	L	X	X	L	M	X	X
3	1234-56-3	L	M	DG	M	DG	DG	X	X	X	X	X	X	L	X	X	DG	L	X	X

X = GS® criteria not applicable for QCAT

Appendix 4: Grading Process

Grade A	a. Low P + Low T (AA, AT and all HH endpoints).
Grade B	a. Moderate P; or b. Moderate B; or c. Moderate AA; or d. Moderate AT or one or more HH endpoints.
Grade C	a. Moderate P + Moderate B + Moderate T (AA, AT, or one of the HH endpoints); or b. High P & High B; or c. High P + Moderate T (AA, AT, or any one of the HH endpoints); or d. High B + Moderate T (AA, AT, or any one of the HH endpoints); or e. Very High T (AA or AT) or High T (any one of the HH endpoints).
Grade F	a. PBT = High P + High B + [Very High T (AA or AT) or High T (HH)]; or b. vPvB = very High P + very High B; or c. vPT = very High P + [very High T (AA or AT) or High T (HH)]; or d. vBT = very High B + [very High T (AA or AT) or High T (HH)]; or e. High T (HH).

[1]Legend:

AA	=	**Acute Aquatic Toxicity**	**D**	=	**Developmental Toxicity (incl. developmental neurotoxicity)**	**M**	=	**Mutagenicity/Genotoxicity**
AT	=	**Acute Mammalian Toxicity**	**E**	=	**Endocrine Activity**	**R**	=	**Reproductive toxicity**
B	=	**Bioaccumulation**	**F**	=	**Flammability**	**vB**	=	**Very Bioaccumulative**
C	=	**Carcinogenicity**	**HH**	=	**Human Health (C, M/G, R, D & E)**	**vP**	=	**Very Persistent**

Note: The assignment of grades is based upon the benchmarking process described in the GS®. The GS® benchmarking process was formulated during extensive discussions with nationally recognized experts in the various hazard criteria. These experts functioned as the Technical Advisory Committee during the update and expansion of the GS® Version 1.2. The intent of this discussion, however, was to provide a reproducible method of assigning degrees of concern based upon the results of the GS® assessment. For the purposes of the QCAT, a similar process is used as found in the GS® after the seven hazard criteria not used in the QCAT have been removed.

Appendix 5: Result of Final QCAT Evaluation for Chemicals in Appendix 3

Chemical	End Use	Initial Grade	Data Gap Grade	Final Grade	Reasons for Grade
Chemical 1	Flame Retardant	**Grade F**	**N/A**	**Grade F**	Very high acute mammalian toxicity, high persistence and bioaccumulation. High for three of the human health endpoints and high acute aquatic toxicity. A data gap analysis is not required as all endpoints have data.
Chemical 2	Flame Retardant	**Grade B**	**Grade B**	**Grade B**	Grade B based upon low human hazard endpoints, low AT and moderate B and low P. There is no change to the initial grade as only one data gap exists and it is not for a required endpoint.
Chemical 3	Flame Retardant	**Grade C**	**Grade F_{dg}**	**Grade F_{dg}**	Grade C due to moderate mutagenicity/genotoxicity and developmental toxicity. Data gaps exist for four criteria including a required endpoint (P). Grade 'F_{dg}' assigned showing lack of confidence in grade assigned based upon existing data.

Grade A	Few concerns, i.e., safer chemical	**Preferable**
Grade B	Slight concern	**Improvement possible**
Grade C	Moderate concern	**Use but search for safer**
Grade F	High concern	**Avoid**

Appendix 6: QCAT Blank Report

(A copy of this document (in Word) is available at _____)

QCAT Evaluation:
Author:
Title:
Organization:
Date:

Peer review:
Reviewer:
Title:
Organization:
Date:

QCAT for Safer Chemicals Example Chemical Assessment Worksheet

Chemical Name:
CAS #:
Also Called:
Identify Applications/Functional Uses:
Chemical Structure:

Hazard Summary Table:

Human - Group 1					Human - Group 2							Eco			Fate		Physical	
C	M	R	D	E	AT	ST	N	SnS	SnR	Irs	IrE	AA	CA	Eo	P	B	Ex	F
						X	X	X	X	X	X		X	X			X	X

Note: Please see Appendix A for glossary of hazard endpoint acronyms.

Initial Grade	
Data Gap Grade	
Final Grade	

Human Health Effects – Group I

Carcinogenicity (C) Hazard Level (H, M, L or DG):

- Research Summary:
- References:

Mutagenicity and Genotoxicity (M) Hazard Level (H, M, L or DG):

- Research Summary:
- References:

Reproductive Toxicity (R) Hazard Level (H, M, L or DG):

- Research Summary:
- References:

Development Toxicity incl. Developmental Neurotoxicity (D) Hazard Level (H, M, L or DG):

- Research Summary:

- References:

Endocrine Disruption (E) Hazard Level (H, M, L or DG):

- Research Summary:

- References:

Human Health Effects – Group II

Acute Mammalian Toxicity (AT) Hazard Level (H, M, L or DG):

- Research Summary:

- References:

Environmental Health Effects

Acute Aquatic (AA) Toxicity Hazard Level: (H, M, L or DG):

- Research Summary:

- References:

Environmental Fate

Persistence (P) Hazard Level: (vH, H, M, L, vL or DG):

- Research Summary:

- References:

Bioaccumulation (B) Potential Hazard Level: (vH, H, M, L, vL or DG):

- Research Summary:

- References:

Appendix:

AA = Acute Aquatic Toxicity
AT = Acute Mammalian Toxicity
B = Bioaccumulation
C = Carcinogenicity
CA = Chronic Aquatic Toxicity
D = Developmental Toxicity (incl. Developmental Neurotoxicity)
E = Endocrine Activity
Eo = Other Ecotoxicity studies
F = Flammability
IrE = Irritation-Eye
IrS = Irritation-Skin
M = Mutagenicity & Genotoxicity
N = Neurotoxicity
P = Persistence
R = Reproductive Toxicity
Rd = Repeat dose
Rx = Reactivity
Sd = Single dose
SnR = Sensitization-Respiratory
SnS = Sensitization-Skin
ST = Systemic Toxicity & Organ Effects (incl. Immunotoxicity)

Appendix 7: Example of a Completed QCAT Report

QCAT for Safer Chemicals Example Chemical Assessment Worksheet

QCAT Evaluation:	**Peer review:**
Author: Alex Stone	**Reviewer:**
Title: Safer Chemical Alternative ChemistTitle:	
Organization: WA Dept. of Ecology	**Organization:**
Date: 8/2008	**Date:**

Chemical Name: bis (2-ethylhexyl) phthalate

CAS #: 117-81-7

Also Called: DEHP; PHTHALIC ACID, BIS(2-ETHYLHEXYL) ESTER; PHTHALIC ACID DIOCTYL ESTER; Octyl phthalate; DI-2-ETHYLHEXYLPHTHALATE; 1,2-BENZENEDICARBOXYLIC ACID, BIS(ETHYLHEXYL) ESTER

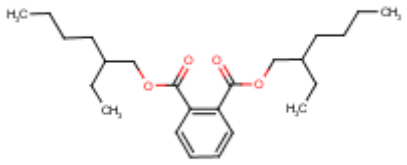
Identify Applications/ Functional Uses:

From HSDB:

Plastics may contain from 1 to 40% di(2-ethylhexyl) phthalateby weight and are used in consumer products such as imitation leather, rainwear, footwear, upholstery, flooring, wire and cable, tablecloths, shower curtains, food packaging materials and children's toys. ... Di(2-ethylhexyl) phthalateis also used as a hydraulic fluid and as a dielectric fluid (a non-conductor of electric current) in electrical capacitors ... a detector for leaks in respirators ...
[IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work). Available at: http://monographs.iarc.fr/index.php p. V77 P43 (2000)]

PLASTICIZER FOR POLYVINYL CHLORIDE RESINS [SRI]
... DEHP is used as a plasticizer in medical devices such as storage containers, bags, and tubing ...
[NTP/CERHR; Monograph on the Potential Human Reproductive and Developmental Effects of Di(2-ethylhexyl) phthalate (DEHP) p. II-1 (2006) NIH Publication No. 06-4476. Available from, as of May 2, 2008: http://cerhr.niehs.nih.gov/evals/index.html

Chemical Structure:



Hazard Summary Table:

Human - Group 1					Human - Group 2							Eco			Fate		Physical	
C	M	R	D	E	AT	ST	N	SnS	SnR	Irs	IrE	AA	CA	Eo	P	B	Ex	F
M	M	H	M	DG	L	X	X	X	X	X	X	L	X	X	H	L	X	X

Note: Please see Appendix A for glossary of hazard endpoint acronyms.

Initial Grade	F
Data gap Grade	N/A[18]
Final Grade	F

Human Health Effects – Group I

Carcinogenicity (C) Hazard Level (M):

- Research Summary:

Based upon the information below, DEHP has a **moderate** level of carcinogenicity concerns. Although DEHP is on the California Prop 65 list, IARC has identified it as a category 2B carcinogen. In this instance, IARC is assumed to be a better qualification of the degree of toxicity and is used to determine the level of concern for DEHP.

- References:

Prop 65	On 65 list
IARC	Category 2B (reported in HSDB)

Mutagenicity and Genotoxicity (M) Hazard Level (M):

- Research Summary:

Although QCAT does not provide any guidance on how to interpret the data below, the data suggests a potential for mutagenicity and genotoxicity; therefore, DEHP is assigned a **moderate** level of concern for these criteria.

- References:

6 mg/L	RTECS: Cytogenetic analysis, human leukocyte
5 umol/L	RTECS: Sister chromatid, human
500 umol/L	RTECS: Unscheduled DNA synthesis, rat liver
14g/,g/14D	RTECS: DNA damage, oral rat, intermittent dosing

Reproductive Toxicity (R) Hazard Level (H):

- Research Summary:

DEHP has been identified by California as a reproductive toxicant and placed on their Prop 65 list; therefore, DEHP is assigned a **high** level of concern for this criteria.

[18] If a chemical obtains a Grade F in its initial evaluation, a data gap analysis is not needed, as any data gaps cannot cause the chemical to receive any lower grade.

- References:

Prop 65	On list
TD_{lo}=6 gm/kg	RTECS: Lowest published toxic dose, oral rat males 3 d. pre-mating, paternal effects
TD_{lo}=17.2 mg/kg	Lowest published toxic dose, oral rat, RTECS; multigenerations, reproductive fertility
TD_{lo}= 0.765 mg/kg	Lowest published toxic dose, oral rat, RTECS; female, 6-22 d. after conception, reproductive effects on newborn

Development Toxicity incl. Developmental Neurotoxicity (D) Hazard Level (M):

- Research Summary:

Although QCAT does not provide any guidance on how to interpret the data below, the data suggests a potential for developmental effects; therefore, DEHP is assigned a **moderate** level of concern for this criterion.

- References:

TD_{lo}= 5 mg/m3 /6H/8D	RTECS: Lowest published toxic conc., inhalation rat, reproductive, maternal effects

Endocrine Disruption (E) Hazard Level (DG):

- Research Summary:

As no data are available from QCAT sources on the impacts of DEHP on the endocrine system, a '**dg**' for data gap is assigned for this criterion.

- References:

Human Health Effects – Group II

Acute Mammalian Toxicity (AT) Hazard Level (L):

- Research Summary:

Based upon the data below, DEHP poses a **low** risk for impacts to acute mammalian toxicity.

- References:

LD_{50}=30,000 mg/kg	oral rat, RTECS
LD_{50}=25,000 mg/kg	dermal rabbit, RTECS

Environmental Health Effects

Acute Aquatic (AA) Toxicity Hazard Level: (L):

- Research Summary:

Based upon the data below, DEHP poses a **low** risk for impacts to acute aquatic toxicity.

- References:

LC_{50}=139-154 mg/L	EPA's ECOTOX: rainbow trout, 23-27 d.

Environmental Fate

Persistence (P) Hazard Level: (H):

- Research Summary:

Based upon the information below, DEHP has a **high** level of persistence, primarily in sediment. As the PBT Profiler is based upon modeling results, additional data would be valuable to confirm this hazard level.

- References:

Half-lives: W 15d, S 30d, Sed 140d, A .75d	EPA's PBT Profiler

Bioaccumulation (B) Potential Hazard Level: (L):

- Research Summary:

Based upon the information below, DEHP has a **low** level of persistence, primarily in sediment.

- References:

BCF=310	EPA's PBT Profiler
BCF=78	EPA's ECOTOX results from tests

Appendix:

AA	=	Acute Aquatic Toxicity
AT	=	Acute Mammalian Toxicity
B	=	Bioaccumulation
C	=	Carcinogenicity
CA	=	Chronic Aquatic Toxicity
D	=	Developmental Toxicity (incl. Developmental Neurotoxicity)
E	=	Endocrine Activity
Eo	=	Other Ecotoxicity studies
F	=	Flammability
IrE	=	Irritation-Eye
IrS	=	Irritation-Skin
M	=	Mutagenicity & Genotoxicity
N	=	Neurotoxicity
P	=	Persistence
R	=	Reproductive Toxicity
Rd	=	Repeat dose
Rx	=	Reactivity
Sd	=	Single dose
SnR	=	Sensitization-Respiratory
SnS	=	Sensitization-Skin
ST	=	Systemic Toxicity & Organ Effects (incl. Immunotoxicity)

Appendix 8: Chemical Ranking Criteria

Human Health: Carcinogenicity			
Very High (v)	**High (H)**	**Moderate (M)**	**Low (L)**
Not applicable	US NIH Report on Carcinogens/NTP RoC Known to be human carcinogen Reasonably anticipated to be human carcinogen Cal/EPA Prop 65 Known to the state to cause cancer EC - REACH SVHC Reason for inclusion: carcinogen		Adequate data available with negative results. DfE General Screen Criteria
	US Center for Disease Control and Prevention (CDC) Occupational Carcinogen	CDC Identified as a potential carcinogen	
	International Agency for Research on Cancer (IARC) Group 1: Known carcinogen Group 2a: Probable carcinogen	IARC Group 2b: Possibly carcinogenic to humans Group 3: Suggestive evidence of carcinogenicity	IARC Group 4: Probably not carcinogenic to humans
	EPA IRIS Carcinogens (1986) Group A: Human carcinogen Group B1: Probable carcinogen Group B2: Probable carcinogen EPA IRIS Carcinogens (1996) Known/likely carcinogen EPA IRIS Carcinogens (1999) or (2005) Carcinogenic to humans Likely to be carcinogenic	EPA IRIS (1986) Group C: Possible human carcinogen IRIS (1999) or (2005) Suggestive evidence of carcinogenicity	EPA IRIS (1986) Group E: Evidence of non-carcinogenicity IRIS (1999) or (2005) Not likely to be carcinogenic to humans
	EC CLP Category 1: Known carcinogenic to man Category 2: Regarded as if carcinogenic to man	EC CLP Category 3: Possibly carcinogenic to man	
	ISSCAN Value Ranking = 3, Carcinogenic	ISSCAN Value Ranking = 2, Undetermined or equivocal	ISSCAN Value Ranking = 1, Non-carcinogenic
	GHS/Japan METI/MOE/Korean NIER/etc. Category 1A: Known to be carcinogenic Category 1B: Presumed to be carcinogenic	GHS/Japan METI/MOE/Korean NIER/etc. Category 2: Suspected carcinogen	GHS/Japan METI/MOE/Korean NIER/etc. No category
	New Zealand HSNO/GHS 6.7A: Known or presumed human carcinogen	New Zealand HSNO/GHS 6.7B: Suspected human carcinogen	New Zealand HSNO/GHS No category
	German MAK Carcinogen Group 1: Cause cancer in man Carcinogen Group 2: Considered to be carcinogenic to man	German MAK Carcinogen Group 3A: Evidence of carcinogenic effects Carcinogen Group 3B: Evidence of carcinogenic effects	
	EC Risk Phrases R45: May cause cancer R49: May cause cancer by inhalation	EC Risk Phrases R40: Limited evidence of carcinogenicity	
	EC – CLP/GHS Hazard Statements H350: May cause cancer H350i: May cause cancer by inhalation	EC – CLP/GHS Hazard Statements H351-Suspected of causing cancer	EC – CLP/GHS Hazard Statements No hazard phrase
	EU RA, IUCLID Datasheet, RTECS, HSDB or UNEP SIDS Strong evidence of carcinogenicity	EU RA, IUCLID Datasheet, RTECS, HSDB or UNEP SIDS Indication of carcinogenicity	EU RA, IUCLID Datasheet, RTECS, HSDB or UNEP SIDS Indication of no carcinogenicity

Human Health: Mutagenicity/Genotoxicity			
Very High (v)	**High (H)**	**Moderate (M)**	**Low (L)**
Not applicable	EC - REACH SVHC Reason for inclusion: Mutagenicity/Genotoxicity		DfE General Screen Criteria
	GHS/Japan METI/MOE/Korean NIER/etc Category 1A: Known to be mutagenic/genotoxic Category 1B: Regarded as if mutagenic/genotoxic	GHS/Japan METI/MOE/Korean NIER/etc Category 2: Suspected mutagenic/genotoxic	GHS/Japan METI/MOE/Korean NIER/etc No category
	New Zealand HSNO/GHS 6.6A: Known or presumed human mutagen	New Zealand HSNO/GHS 6.6B: Suspected human mutagen	New Zealand HSNO/GHS No category
	EC CMR (1) Category 1: Known to be mutagenic to man Category 2: Regarded as if they are mutagenic to man	EC CMR (1) Category 3: Suspected to be mutagenic to man	
	GHS/EC CMR (2) Category 1A: Known to induce heritable mutations Category 1B: Presumed to induce heritable mutations	GHS/EC CMR (2) Category 2: Suspected to induce heritable mutations	
	ISSCAN SAL Value Ranking = 3, Mutagenic	ISSCAN Value Ranking = 2, Undetermined or equivocal	ISSCAN Value Ranking = 1, Non-mutagenic
	German MAK Value Germ Cell Mutagen 1 Germ Cell Mutagen 2	German MAK Value Germ Cell Mutagen 3a Germ Cell Mutagen 3b	
	EC Risk Phrases R46: May cause heritable genetic damage	EC Risk Phrases R68: Strong evidence of heritable genetic damage	EC Risk Phrases No risk phrase
	EC – CLP/GHS Hazard Statements H340-May cause genetic defects	EC – CLP/GHS Hazard Statements H341-Suspected of causing genetic defects	EC – CLP/GHS Hazard Statements No hazard phrase
	EU RA, IUCLID Datasheet, RTECS, HSDB or UNEP SIDS Strong evidence of mutagenicity/genotoxicity	EU RA, IUCLID Datasheet, RTECS, HSDB or UNEP SIDS Indication of mutagenicity/genotoxicity	EU RA, IUCLID Datasheet, RTECS, HSDB or UNEP SIDS Adequate data available and negative studies

Human Health: Reproductive Toxicity			
Very High (v)	**High (H)**	**Moderate (M)**	**Low (L)**
Not applicable	Cal/EPA – Prop 65 Known to the state to cause reproductive effects-male or female EC - REACH SVHC[19] Toxic for reproduction		DfE General Screen Criteria
	US NIH Repo. & Dev. Monographs/NTP-OHAaT Category A: Clear evidence of Adverse Effects-Reproductive Toxicity	US NIH Repo. & Dev. Monographs/NTP-OHAaT Category B: Limited or some evidence of Adverse Effects-Repro Toxicity	US NIH Repo. & Dev. Monographs/NTP-OHAaT Category D: Clear evidence of No Adverse Effects-Repro. Toxicity
	EC CMR (1) Category 1: Known to impair fertility or cause developmental toxicity Category 2: Regarded as impairing fertility or cause developmental toxicity	EC CMR (1) Category 3: Suspected to impair fertility or cause developmental toxicity in humans	
	GHS/Japan METI/MOE/Korean NIER/etc Category 1A: Known reproductive toxicant Category 1B: Presumed reproductive toxicant	GHS/Japan METI/MOE/Korean NIER/etc Category 2: Suspected repro toxicant, or has effect on lactation	GHS/Japan METI/MOE/Korean NIER/etc No category
	New Zealand HSNO/GHS 6.8A: Known or presumed human repro. or developmental toxicants 6.8C: Produce human repro. or dev. effects on or via lactation	New Zealand HSNO/GHS 6.8B: Suspected human reproductive or developmental toxicants	
	EC Risk Phrases R60: May impair fertility	EC Risk Phrases R62: Possible risk of impaired fertility	EC Risk Phrases No risk phrase
	EC – CLP/GHS Hazard Statements H360F: May damage fertility H360FD: May damage fertility or the unborn child H360Fd: May damage fertility. Suspected of damaging unborn child	EC – CLP/GHS Hazard Statements H360 Df-May damage unborn. Suspected of damaging fertility. H361f-Suspected of damaging fertility H361fd-Suspected of damaging fertility & unborn child	EC – CLP/GHS Hazard Statements No hazard phrase
	EPA Characterization Criteria: LOAEL, TD_{lo} or TC_{lo}Values Oral < 50 mg/kg-bw/d Dermal < 100 mg/kg-bw/d Inhalation (vapor) < 1.0 mg/L/d Inhalation (dust/mist/fume) < 0.1 mg/L/d Inhalation (gas) < 50 ppm/d	EPA Characterization Criteria: LOAEL, TD_{lo} or TC_{lo}Values Oral ≥ 50 but< 250 mg/kg-bw/d Dermal ≥ 100but< 500 mg/kg-bw/d Inhalation (vapor) ≥ 1.0 but< 2.5 mg/L/d Inhalation (dust/mist/fume) ≥ 0.1 but< 0.5 mg/L/d Inhalation (gas) ≥ 50 but< 250 ppm/d	EPA Characterization Criteria: LOAEL, TD_{lo} or TC_{lo}Values Oral ≥ 250mg/kg-bw/d Dermal ≥ 500 mg/kg-bw/d Inhalation (vapor) ≥ 2.5 mg/L/d Inhalation (dust/mist/fume) ≥ 0.5 mg/L/d Inhalation (gas) ≥ 250 ppm/d
	EU RA, IUCLID Datasheet, RTECS, HSDB or UNEP SIDS Strong evidence of repro/developmental toxicity	EU RA, IUCLID Datasheet, RTECS, HSDB or UNEP SIDS Indication of repro/developmental toxicity	EU RA, IUCLID Datasheet, RTECS, HSDB or UNEP SIDS Indication of no repro/developmental toxicity

[19] ECHA listings and EU CMRs include both reproduction and developmental effects in one grouping under a broad definition of 'Reproductive toxicity'. For the purposes of QCAT, the distinction between whether these are listings are actually due to reproductive or developmental effects is left for a more detailed assessment such as the GS®. The QCAT will assume that all of the effects are grouped here.

Human Health: Developmental (including Developmental Neurotoxicity)			
Very High (v)	**High (H)**	**Moderate (M)**	**Low (L)**
Not applicable	CA/EPA - Prop 65 Known to the state to cause reproductive effects-developmental Lancet - Grandjean & Landrigan list Presence on list		DfE General Screen Criteria
	US NIH Repo. & Dev. Monographs/NTP-OHAaT Cat. A: Clear evidence of Adverse Effects-Developmental	US NIH Repo. & Dev. Monographs/NTP-OHAaT Cat. B: Some evidence of Adverse Effects-Developmental Cat. C. Limited evidence of Adverse Effects-Developmental	US NIH Repo. & Dev. Monographs/NTP-OHAaT Cat. E: Limited or some of No Adverse Effects-Developmental Cat. F: Some evidence of No adverse Effects-Developmental Cat. G: Clear evidence of No Adverse Effects- Developmental
	GHS/Japan METI/MOE/Korean NIER/etc Category 1A: Known developmental toxicant Cat. 1B: Presumed developmental toxicant	GHS/Japan METI/MOE/Korean NIER/etc Cat. 2: Suspected developmental toxicant, or has effect on lactation	GHS/Japan METI/MOE/Korean NIER/etc No category
	EC Risk Phrases R61: May cause harm to unborn child R64: May cause harm to breast-fed babies	EC Risk Phrases R63: Possible risk of harm to unborn child	EC Risk Phrases No risk phrase
	EC – CLP/GHS Hazard Statements H360D: May damage the unborn child H360FD: May damage fertility or the unborn child HD360Df: May damage unborn child or suspected of damaging fertility H362: May cause harm to breast-fed children	EC – CLP/GHS Hazard Statements H360Fd-Suspected of impacting fertility or unborn child H361d-Suspected of damaging fertility or unborn child H361fd-Suspected of damaging fertility & unborn child	EC – CLP/GHS Hazard Statements No hazard phrase
	EU RA, IUCLID Datasheet, RTECS, HSDB or UNEP SIDS Strong evidence of repro/developmental toxicity	EU RA, IUCLID Datasheet, RTECS, HSDB or UNEP SIDS Indication of repro/developmental toxicity	EU RA, IUCLID Datasheet, RTECS, HSDB or UNEP SIDS Indication of no repro/developmental toxicity

Human Health: Endocrine Activity			
Very High (v)	**High (H)**	**Moderate (M)**	**Low (L)**
Not applicable	EC/Oslo-Paris Conv. List of Endocrine Disruptors EC - REACH SVHC Reason for inclusion: Endocrine Activity		Meets DfE General Screen Criteria for each endpoint related to an endocrine system mediated effect (e. g., carcinogenicity, reproductive/develop-mental toxicity, repeated dose toxicity)
	EC – Priority Endocrine Disruptors Category 1: Evidence of endocrine disruption	EC – Priority Endocrine Disruptors Cat. 2: Some evidence of biologically activity Cat. 3b: Some evidence of endocrine activity	EC – Priority Endocrine Disruptors Cat. 3C: Data indicating no basis for inclusion on list
	EU RA, IUCLID Datasheet, RTECS, HSDB or UNEP SIDS Evidence of endocrine activity &related human health effect	EU RA, IUCLID Datasheet, RTECS, HSDB or UNEP SIDS Some evidence of endocrine activity and effects	EU RA, IUCLID Datasheet or UNEP SIDS Adequate data available-evidence of no endocrine activity

Human Health: Acute Mammalian Toxicity			
Very High (v)	**High (H)**	**Moderate (M)**	**Low (L)**
No authoritative lists available	EPA EPCRA Section 302 Priority Chemicals Presence on the list		No authoritative lists available DfE General Screen Criteria
EC – CLP/GHS Category 1 Category 2	EC – CLP/GHS Category 3	EC – CLP/GHS Category 4	EC – CLP/GHS Category 5
EC Risk Phrases R26-Very toxic via inhalation R27-Very toxic via skin R28-Very toxic if swallowed	EC Risk Phrases R23-Toxic via inhalation R24-Toxic via skin R25-Toxic if swallowed	EC Risk Phrases R20- Harmful via inhalation R21- Harmful via skin R22- Harmful if swallowed	EC Risk Phrases No Risk Phrase
EC – CLP/GHS Hazard Statements H300-Fatal if swallowed H310-Fatal in contact with skin H330-Fatal if inhaled	EC – CLP/GHS Hazard Statements H301-Toxic if swallowed H311-Toxic in contact with skin H331-Toxic if inhaled	EC – CLP/GHS Hazard Statements H302-Harmful if swallowed H312-Harmful in contact with skin H332-Harmful if inhaled	EC – CLP/GHS Hazard Statements H303-May be harmful if swallowed H313-May be harmful in contact with skin H333-May be harmful if inhaled
Technical Criteria Oral $LD_{50} \leq 50$ mg/kg bw Dermal $LD_{50} \leq 200$ mg/kg bw Inhalation (g) $LC_{50} \leq 500$ ppm Inhalation (v) $LC_{50} \leq 2.0$ mg/l Inhalation (dust, mist) $LC_{50} \leq 0.5$ mg/l	Technical Criteria Oral $LD_{50} > 50$ but ≤ 300 mg/kg bw Dermal $LD_{50} > 200$ but $\leq 1{,}000$ mg/kg bw Inhalation (g) $LC_{50} > 500$ but $\leq 2{,}500$ ppm Inhalation (v) $LC_{50} > 2.0$ but ≤ 10.0 mg/l Inhalation (dm) $LC_{50} > 0.5$ but ≤ 1.0 mg/l	Technical Criteria Oral $LD_{50} > 300$ but $\leq 2{,}000$ mg/kg bw Dermal $LD_{50} > 1{,}000$ but $\leq 2{,}000$ mg/kg bw Inhalation (g) $LC_{50} > 2{,}500$ but $\leq 20{,}000$ ppm Inhalation (v) $LC_{50} > 10.0$ but ≤ 20.0 mg/l Inhalation (dm) $LC_{50} > 1.0$ but ≤ 5.0 mg/l	Technical Criteria Oral $LD_{50} > 2{,}000$ mg/kg bw Dermal $LD_{50} > 2{,}000$ mg/kg bw Inhalation (g) $LC_{50} > 20{,}000$ ppm Inhalation (v) $LC_{50} > 20.0$ mg/l Inhalation (dm) $LC_{50} > 5.0$ mg/l
	EU RA, IUCLID Datasheet, RTECS, HSDB or UNEP SIDS Strong evidence of acute mammalian toxicity	EU RA, IUCLID Datasheet, RTECS, HSDB or UNEP SIDS Indication of acute mammalian toxicity	EU RA, IUCLID Datasheet, RTECS, HSDB or UNEP SIDS Indication of no acute mammalian toxicity

Environmental Health: Acute Aquatic Toxicity			
Very High (v)	**High (H)**	**Moderate (M)**	**Low (L)**
Environment Canada-Domestic Substances List Chemicals Identified as Inherently Toxic to Aquatic Organisms, presence on list			Environment Canada-Domestic Substances List Identified as not meeting inherently toxic criteria
EC – CLP/GHS Category 1: Very toxic to aquatic life	EC – CLP/GHS Category 2: Toxic to aquatic life	EC – CLP/GHS Category 3: Harmful to aquatic life	EC – CLP/GHS No criteria
New Zealand HSNO/GHS 9.1A: Very ecotoxic in the aquatic environment	New Zealand HSNO/GHS 9.1B: Ecotoxic in the aquatic environment	New Zealand HSNO/GHS 9.1C: Harmful in the aquatic environment	
EC Risk Phrases R50-Very toxic to aquatic organisms	EC Risk Phrases R51-Toxic to aquatic organisms	EC Risk Phrases R52-Harmful to aquatic organisms	EC Risk Phrases No risk phrase
EC – CLP/GHS Hazard Statements H400: Very toxic to aquatic life	EC – CLP/GHS Hazard Statements H401: Toxic to aquatic life	EC – CLP/GHS Hazard Statements H402: Harmful to aquatic life	EC – CLP/GHS Hazard Statements No hazard phrase
Technical Criteria 96 hr LC_{50} (f[20]) ≤ 1 mg/l 48 hr EC_{50} (c[21]) ≤ 1 mg/l 72 or 96 ErC_{50} (a[22]) ≤ 1 mg/l	Technical Criteria 96 hr LC_{50} (f) >1 but≤ 10 mg/l 48 hr EC_{50} (c) > 1 but≤ 10 mg/l 72 or 96 ErC_{50} (a) > 1 but≤ 10 mg/l	Technical Criteria 96 hr LC_{50} (f) > 10 but≤ 100 mg/l 48 hr EC_{50} (c) > 10 but≤ 100 mg/l 72 or 96 ErC_{50} (a) > 10 but≤ 100 mg/l	Technical Criteria 96 hr LC_{50} (f) > 100 mg/l 48 hr EC_{50} (c) > 100 mg/l 72 or 96 ErC_{50} (a) > 100 mg/l
	EU RA, IUCLID Datasheet, RTECS, HSDB or UNEP SIDS Strong evidence of acute aquatic toxicity	EU RA, IUCLID Datasheet, RTECS, HSDB or UNEP SIDS Indication of acute aquatic toxicity	EU RA, IUCLID Datasheet, RTECS, HSDB or UNEP SIDS Indication of no acute aquatic toxicity

[20] f = fish
[21] c = crustacea
[22] a = algae or other aquatic plants

Environmental Fate: Persistence				
Very High (v)	**High (H)**	**Moderate (M)**	**Low (L)**	**Very Low (vL)**
Stockholm POPs Presence on list EPA Toxics Release Inventory PBTs Presence on list EPA Priority PBTs Presence on list EU PBT List Presence on list WA DoE PBTs Presence on list EC - REACH SVHC vPvB List Presence on list Oregon P3 List Presence on list EC - REACH SVHC vPvB or PBT	Environment Canada-Domestic Substances List PBiT List Presence on list Environment Canada-Domestic Substances List PT List Presence on list EC/Oslo-Paris Conv. Chemicals of Possible Concern PBT List Presence on list EC/Oslo-Paris Conv. Chemicals for Priority Action List Presence on list		Meets GHS Definition for Rapid Degradability	Meets 10-day window as measured in a ready biodegradation
Technical Criteria Half-life (ss[23]) > 180 days Half-life (w[24]) > 60 days Half-life (a[25]) > 5 days	Technical Criteria Half-life (ss) > 60 to 180 days Half-life (w) > 40 to 60 days Half-life (a[26]) > 2 to 5 days Evidence for long-range environmental transport	Technical Criteria Half-life (ss) > 16 to 60 days Half-life (w) > 16 to 40 days Suggestive evidence for long-range environmental transport	Technical Criteria Half-life (ss) < 16 days Half-life (w) < 16 days Half-life (a) < 2 days	
	EU RA, IUCLID Datasheet, RTECS, HSDB or UNEP SIDS Strong evidence of persistence	EU RA, IUCLID Datasheet, RTECS, HSDB or UNEP SIDS Indication of persistence	EU RA, IUCLID Datasheet, RTECS, HSDB or UNEP SIDS Indication of no persistence	

[23] ss = soil or sediment
[24] w = water
[25] a = air
[26] a = air

Environmental Fate: Bioaccumulation				
Very High (v)	**High (H)**	**Moderate (M)**	**Low (L)**	**Very Low (vL)**
Stockholm POPs Presence on list EPA TRI PBT List Presence on list EPA PBT List Presence on list EU PBT List Presence on list WA DoE PBTs Presence on list EC - REACH SVHC vPvB List Presence on list EC - REACH SVHC vPvB or PBT	Environment Canada-Domestic Substances List PB$_i$T List Presence on list Environment Canada-Domestic Substances List B$_i$T List Presence on list EC/Oslo-Paris Conv. Chemicals of Possible Concern PBT List Presence on list EC/Oslo-Paris Conv. Chemicals for Priority Action List Presence on list			
Technical Criteria BCF/BAF ≥ 5,000 Log K_{ow}[27] ≥ 5	Technical Criteria BCF/BAF ≥ 1,000 but < 5,000 Log K_{ow} ≥ 4.5 but < 5 Weight of evidence-presence in humans &wildlife	Technical Criteria BCF/BAF ≥ 500 but < 1,000 Log K_{ow} ≥ 4 but < 4.5 Suggestive evidence-presence in humans &wildlife	Technical Criteria BCF/BAF ≥ 100 but < 500	Technical Criteria: BCF/BAF < 100 Log K_{ow} < 4
	EU RA, IUCLID Datasheet, RTECS, HSDB or UNEP SIDS Strong evidence of bioaccumulation	EU RA, IUCLID Datasheet, RTECS, HSDB or UNEP SIDS Indication of bioaccumulation	EU RA, IUCLID Datasheet, RTECS, HSDB or UNEP SIDS Indication of no bioaccumulation	

[27] Log K_{ow} = logarithm of the octanol/water partition coefficient